EFSA Panel on Biological Hazards; Scientific Opinion on a Quantitative Microbiological Risk Assessment of Salmonella in slaughter and breeder pigs

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SCIENTIFIC OPINION

Scientific Opinion on a Quantitative Microbiological Risk Assessment of *Salmonella* in slaughter and breeder pigs[1]

EFSA Panel on Biological Hazards (BIOHAZ)[2, 3]

European Food Safety Authority (EFSA), Parma, Italy

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ABSTRACT

This Quantitative Microbiological Risk Assessment (QMRA) represents a major step forward in terms of modelling *Salmonella* in pigs from farm to consumption as it takes into account the variability between and within EU Member States (MSs). Around 10-20% of human *Salmonella* infections in EU may be attributable to the pig reservoir as a whole. From the QMRA analysis it appears that an 80% or 90% reduction of lymph node prevalence should result in a comparable reduction in the number of human cases attributable to pig meat products. Theoretically, according to the QMRA the following scenarios appear possible (a) by ensuring that breeder pigs are *Salmonella*-free a reduction of 70-80% in high prevalence MSs and 10-20% in low prevalence MSs can be foreseen; (b) by feeding only *Salmonella*-free feedstuffs, a reduction of 10-20% in high prevalence MSs and 60-70% in low prevalence MSs can be foreseen; and (c) by preventing infection from external sources of *Salmonella* (i.e. rodents and birds) a reduction of 10-20% in slaughter pig lymph node prevalence can be foreseen in both high and low prevalence MSs. A hierarchy of control measures is suggested - a high prevalence in breeder pigs needs to be addressed first, followed by control of feed and then control of environmental contamination. Also according to the QMRA, for each MS, a reduction of two logs (99%) of *Salmonella* numbers on contaminated carcasses would result in more than 90% reduction of the number of human salmonellosis cases attributable to pig meat consumption. The control of *Salmonella* in pig reservoir in the EU is a reasonable objective. The EU *Salmonella* control strategy in pigs should be continuously evaluated to identify possible improvements.

KEY WORDS

Salmonella, pigs, pig meat, QMRA, control, prevention, risk assessment, epidemiology

1 On request from the European Commission, Question No EFSA-Q-2006-176, originally adopted on 11 March 2010. After identification of modelling errors in the QMRA report by the consortium (grant beneficiary), this opinion was corrected, the current annex with explanations for the corrections of the errors added, and the corrected opinion adopted on 21 October 2010. The changes were made in Section 6 and corresponding conclusions, and are specified in Appendix C and Appendix E.

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SUMMARY

Following a request from the European Commission, the Panel on Biological Hazards was asked to deliver a scientific opinion on a Quantitative Microbiological Risk Assessment (QMRA) of *Salmonella* in slaughter and breeder pigs. The assessment would provide the input for a future cost/benefit analysis of setting a target for reduction in slaughter pigs at EU level. EFSA commissioned a QMRA modelling the pig meat food chain from farm to fork. The QMRA model was based on input data from the baseline studies of *Salmonella* in breeder and slaughter pigs, and other relevant data. The QMRA represents a major step forward in terms of modelling *Salmonella* in pigs from farm to consumption as it takes into account the variability between and within EU Member States (MSs). Transmission of *Salmonella* was analysed using the individual pig as the unit of interest. There are data gaps and critical assumptions in the model, and these should be carefully considered when interpreting the results of the model.

The fraction of human salmonellosis cases attributable to *Salmonella* in pigs and pig meat will vary considerably between MSs and will mainly depend on i) the *Salmonella* occurrence (prevalence and numbers) in pigs and pig meat, ii) consumption patterns and preferences and iii) the relative importance of other *Salmonella* sources. From the descriptive and comparable analysis of the serovar distribution in animal sources and humans, a cautious assessment would be that around 10-20% of human *Salmonella* infections in EU may be attributable to the pig reservoir as a whole.

However, the use of this estimate necessitates caution due to the lack of MS-specific data on the distribution of serovars in humans. From the QMRA analysis it appears that an 80% or 90% reduction of lymph node prevalence should result in a comparable reduction in the number of human cases attributable to pig meat products.

Breeder pig herd prevalence is a major determinant of slaughter pig lymph node prevalence at EU level. The importance appears to be more obvious in high prevalence countries as a 90% reduction of the breeder pig herd prevalence could theoretically result in a reduction in an order of magnitude of two thirds of slaughter pig lymph node *Salmonella* prevalence. The major sources of infection for breeder pigs are the same as for slaughter pigs; infected incoming pigs and *Salmonella* contaminated feed, plus other external and internal sources. *Salmonella* control in breeder pig farms need to focus on the following key control measures (1) control of *Salmonella* in nucleus and multiplier herds; (2) control of *Salmonella* in incoming pigs (knowledge of *Salmonella* status); (3) control of *Salmonella* in feed; and (4) biosecurity programs should include the control of *Salmonella*.

To achieve control of *Salmonella* in slaughter pigs the two major sources should be controlled: *Salmonella*-infected breeder pig herds, and *Salmonella*-contaminated feed.

Theoretically, according to the QMRA following scenarios appear possible (a) by ensuring that breeder pigs are *Salmonella*-free a reduction of 70-80% in high prevalence MSs and 10-20% in low prevalence MSs can be foreseen; (b) by feeding only *Salmonella*-free feedstuffs, a reduction of 10-20% in high prevalence MSs and 60-70% in low prevalence MSs can be foreseen; and (c) by preventing infection from external sources of *Salmonella* (i.e. rodents and birds) a reduction of 10-20% in slaughter pig lymph node prevalence can be foreseen in both high and low prevalence MSs. A hierarchy of control measures is suggested - a high prevalence in breeder pigs needs to be addressed first, followed by control of feed and then control of environmental contamination. Also according to the QMRA, for each MS, a reduction of two logs (99%) of *Salmonella* numbers on contaminated carcasses would result in a more than 90% reduction of the number of human salmonellosis cases attributable to pig meat consumption. A reduction of one log (90%) would result in more than 80% reduction of human cases. This could be achieved through measures preventing direct and/or indirect faecal contamination during transport, lairage and, particularly, slaughter and dressing processes; and/or by effective carcass decontamination.

Control of *Salmonella* in pig meat as a public health problem should be based on the individual MSs situations and include combinations of following interventions: *Salmonella*-free (low risk) breeder pigs, *Salmonella*-free feed, cleaning-disinfection between batches both on-farm and during lairage, avoidance of faecal contamination during slaughter and decontamination of the carcasses. Efficient vaccination will also be useful to control *Salmonella* on farm, but might interfere with the interpretation of serological test results in monitoring/surveillance programmes. The QMRA results could give some guidance on appropriate combinations. From the current evidence, it would appear that specific slaughterhouse interventions are, at present, more likely to produce greater and more reliable reductions in human illness, at least in a shorter timeframe, than can be achieved at the farm in high prevalence MSs. However, the hypothetical reductions and multiple interventions investigated with the current risk assessment model suggest that MSs can achieve more effective reductions in human cases by targeting both farm and slaughterhouse. MSs should have the possibility to assess their national pig meat food chains using this QMRA model.

The slaughterhouse remains a critical step of the pig meat chain in respect to pig and carcass contamination and numerous aspects (e.g. airborne transmission of *Salmonella* in the abattoir) still remain unknown. Therefore studies need to be performed to properly assess the ways carcasses become contaminated.

The control of *Salmonella* in pig reservoir in the EU is a reasonable objective. The EU *Salmonella* control strategy in pigs should be continuously evaluated to identify possible improvements.

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BACKGROUND AS PROVIDED BY THE EUROPEAN COMMISSION

A total of 192,703 human cases of salmonellosis were reported in the EU in 2004[4], food being the main source of infection. It is estimated that several thousand people die each year in the EU due to salmonellosis. Eggs, egg products, poultry meat and pig meat are the main source of outbreaks in humans from products of animal origin.

Regulation No 2160/2003[5] lays down provisions for the control of *Salmonella* and other specified food-borne agents. The scope of the Regulation is limited to agents which pose a public health concern. The Regulation requires the setting of Community targets for the reduction of the prevalence of zoonoses and zoonotic agents at the level of primary production and where appropriate, at other stages of the food chain. Target setting in poultry populations (breeding hens, laying hens, broilers and turkeys) is ongoing. However, the current provisions also require the setting of targets for *Salmonella* in live pigs within a fixed time schedule. Before defining a Community target, an analysis of its expected costs and benefits must be provided.

In view of this future cost/benefit analysis, it seems appropriate to carry out quantitative risk assessments on *Salmonella* in slaughter and breeder pigs. In accordance with Article 15 of Regulation (EC) No 2160/2003, EFSA shall be consulted before a target for reduction is set. Therefore, EFSA, in particular its Panel on Biological Hazards, is requested to carry out this quantitative risk assessment. The cost/benefit analysis itself is not part of this mandate.

Information on *Salmonella* prevalence and its risk factors in the pig populations is needed to carry out the risk assessment. In this regard, baseline studies have been scheduled in order to obtain comparable data on the prevalence and risk factors in pigs in all Member States (MSs). EFSA is involved in the drafting of the technical specifications of the baseline studies and in the assessment of the results. Data on epidemiological trends may be collected from the annual reports of the Member States, drafted in accordance with the provisions in Directives 92/117/EEC[6] and 2003/99/EC[7]. At the request of the Commission, risk factors and control options for *Salmonella* in pigs were also addressed in the Opinion of the Scientific Panel on Biological Hazards related to "Risk assessment and mitigation options of *Salmonella* in pig production"[4]. However, quantitative evaluations are only briefly considered in this opinion.

TERMS OF REFERENCE AS PROVIDED BY THE EUROPEAN COMMISSION

The European Food Safety Authority is asked to carry out a quantitative risk assessment on *Salmonella* in slaughter and breeder pigs.

Slaughter pigs

The objective of this request is to carry out a quantitative assessment of the public health risk of the presence of *Salmonella* in slaughter pigs, including a quantitative estimation of the risk factors and the effect of mitigation options. The assessment should provide the input for a future cost/benefit analysis of setting a target for reduction in slaughter pigs at EU level.

A baseline study to collect comparable information on the prevalence of *Salmonella* in slaughter pigs in all Member States will be carried out from October 2006 until September 2007 in accordance with Decision 2006/668/EC[8]. The technical specifications were based on EFSA's proposal in Annex III to the opinion of the BIOHAZ Panel on *Salmonella* in pigs and involve bacteriological analyses of ileo-caecal lymph nodes at slaughter and serology on meat juice. The Community Reference Laboratory

4 The EFSA Journal (2006), 341, 1-131. The numbers have been updated in the following reports.
5 OJ L 325, 12.12.2003, p. 1. Regulation as amended by Commission Regulation (EC) No 1003/2005 (OJ L 170, 1.7.2005, p. 12)
6 OJ L 62, 15.3.1993, p. 38, Directive as last amended by Regulation(EC) No 806/2003 (OJ L 122, 16.5.2003, p. 1)
7 OJ L 325, 12.12.2003, p. 31.
8 OJ L 275, 6.10.2006, p. 51

intends to also make comparative studies on different serological tests in 2007. Prevalence data from all Member States based on these two analyses seem therefore the most appropriate reference data if targets for reduction are considered.

Using information from the baseline study, the data mentioned in section 1 and any other information considered relevant, a quantitative estimation at Community level is requested of:

- the relative contribution of *Salmonella* infections in slaughter pigs on *Salmonella* cases in humans. If an estimation of the influence of the prevalence of *Salmonella* in pigs at slaughter on human cases is not possible within the indicated time schedule, the influence on *Salmonella* prevalence in pig meat at retail should be estimated;

- the expected reduction of *Salmonella* cases in humans (or pig meat at retail) by a reduction (e.g. 5- or 10-fold) of *Salmonella* prevalence in slaughter pigs (based on bacteriology in lymph nodes or serology at slaughter);

- the sources of infection for fattening pigs at farm level;

- the reduction of the prevalence in slaughter pigs by the most important potential treatments or control measures at farm level:

- the impact of transport, lairage and slaughter processes on contamination of carcasses;

- the expected reduction of *Salmonella* cases in humans (or pig meat) by the most important potential control options during transport, at lairage or during the slaughter process.

All serotypes in pigs that are of human health significance should be considered together.

Breeder pigs

The objective of this request is to carry out a quantitative assessment on the risk of the presence of *Salmonella* in breeder pigs as a source of infection for slaughter pigs, including a quantitative estimation of risk factors and the effect of mitigation options. The assessment should provide the input for a future cost/benefit analysis of setting a target for reduction in breeder pigs at EU level.

A baseline study to collect comparable information on the prevalence of *Salmonella* in breeder pigs in all Member States is scheduled from October 2007 until September 2008. EFSA has been requested to propose technical specifications for such a baseline study.

Using information from the baseline study and any other information considered relevant, a quantitative estimation at Community level is requested of:

- the relative contribution of *Salmonella* infections in breeder pigs on *Salmonella* prevalence in slaughter pigs (based on bacteriology in lymph nodes or serology at slaughter);

- the expected reduction of *Salmonella* prevalence in slaughter pigs (based on bacteriology in lymph nodes or serology at slaughter) by a reduction (e.g. 5- or10-fold) of *Salmonella* prevalence in breeder pigs;

- the sources of infection for breeder pigs and piglets at farm level;

- the reduction of the prevalence in breeder pigs and piglets by the most important potential treatments or control measures at farm level.

All serotypes in pigs that are of human health significance should be considered together.

The Commission will forward the results of the baseline study before the end of 2008. It is requested that the quantitative assessment is carried out before the end of June 2009[9], allowing the Commission to carry out a cost/benefit analysis and set a target for reduction within its legal constraints.

9 The European Commission has agreed to postpone the date for delivery of the scientific opinion to 31 March 2010

ASSESSMENT

1. Introduction

The data collected by the Community system for zoonoses monitoring show that salmonellosis remains a very important zoonotic disease in humans with 131,468 confirmed cases in the EU in 2008 (notification rate 26.4 per 100,000 population), topped only by campylobacteriosis with 190,566 confirmed cases. The total number of reported human salmonellosis cases in the EU has decreased steadily by several thousand cases annually since 2004, from 195,946[10] cases in 2004 to 133,258 in 2008. The reporting of confirmed human salmonellosis cases in 2008 represents a 13.5% decrease from 2007 in Member States (MSs) (EFSA, 2010).

Salmonella was the most common reported causative agent for food-borne outbreaks in the EU in 2008, being responsible for 35.4% of all reported outbreaks. A total of 490 verified *Salmonella* outbreaks were reported by MSs, corresponding to 26.0% of the total reported *Salmonella* outbreaks. 7.1% of human cases caused by *Salmonella* were attributed to pig meat and products (12.2% of human cases caused by *S.* Typhimurium and 2.2% of cases caused by *S.* Enteritidis were attributed to pig meat and products). In contrast, *Campylobacter* caused 9.2% of all reported outbreaks and 2.4% of verified outbreaks (EFSA, 2010).

Table 1: Number of confirmed salmonellosis cases in humans 2005-2008 (EFSA, 2010)

	2005	2006	2007	2008
Number of confirmed cases in the EU	174,544	164,011	151,998	131,468

EFSA and previously the SANCO Scientific Committee on Veterinary Measures relating to Public Health (SCMVPH) have issued several opinions on *Salmonella* during the last 15 years, such as the opinions on food borne zoonoses, *Salmonella* and its main sources, *Salmonella* in the poultry and pig meat food chains.

Salmonella-reducing control measures early in the food chain may not always reduce the public health risks. This is because *Salmonella* can multiply and survive along the food chain, behaving as an infectious agent in the pre-harvest stage and as a food contaminant in the harvest and post-harvest stages.

To assess the impact of *Salmonella* targets and the public health risk measured as incidence of human salmonellosis, EFSA commissioned a quantitative microbial risk assessment (QMRA) from a consortium consisting of RIVM, Food DTU and VLA, modelling the pig meat food chain from farm to fork. The QMRA model should be based on input data from the baseline studies of *Salmonella* in breeder and slaughter pigs, and other relevant data. This is one of the first comprehensive farm-to-fork models where the consumer risk for *Salmonella* in pig meat has been explicitly modelled at the EU level.

This QMRA represents a major step forward in terms of modelling *Salmonella* in the pig meat food chain.

The challenge has been to derive a relevant model, i.e. a set of equations given current knowledge of the pig meat food chain, and thereafter to use the model equations to make valid inferences on the effects of *Salmonella* control measures within the EU pig meat food chain.

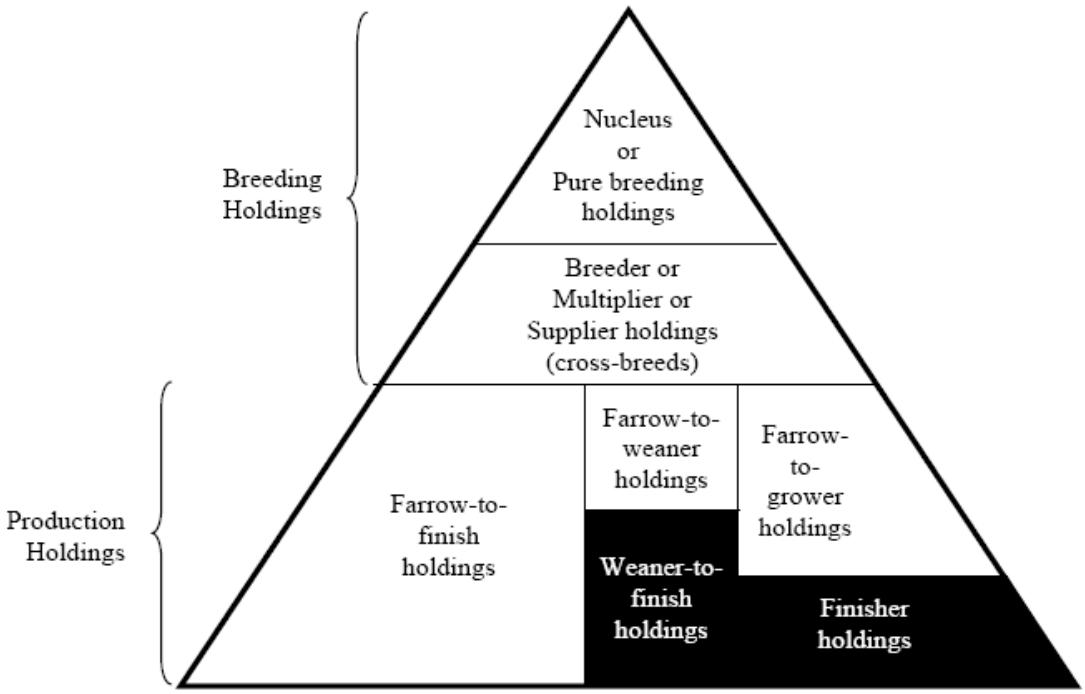
10 This number (195,946 cases of human salmonellosis) is higher than given in the background in this opinion (192,703 cases) since the number of human cases is continuously updated as more information becomes available.

The *Salmonella* risk resulting from the slaughtering of breeder pigs (sows, boars) was not considered in the model. Furthermore, the QMRA did not look at the production system of breeder pigs. The breeder pig prevalence is only used as a variable for source of infection of slaughter pigs.

The QMRA model was developed as a generic model. It is flexible enough to be adopted and used by any MS, using their specifications and data, if available.

A further refinement of the model would be to model the impact of the breeding pyramid in pig production. At the top in this pyramid (Figure 1) are "*elite breeding, or nucleus, herds"* that follow special selection procedures, deliver boars for production of semen at boar stations. These herds can also deliver purebred boars and gilts to all other 'production holdings (farrow-to-finish, farrow-to-weaner and farrow-to-grower holdings).

Beneath this 'elite breeding' there are "*multiplier herds*". These herds deliver replacement animals to all production herds. The latter herds, often referred to as "*commercial, or piglet-producing herds*", produce piglets and keep them until weaning (farrow-to-weaner), until the first stage of fattening (farrow-grower holdings) or covering the whole production phase (farrow-to-finish). The latter and the weaner-to-finish holdings as well as the finisher holdings produce pigs that are called in this report slaughter pigs and are sent to slaughter at the end of the growing/finishing period. Some of the piglet-producing herds, can also have units for slaughter pigs, and are usually called "*integrated herds or farrow-to-finish herds*".



Overview of the pig breeding and production holdings included in the EU MRSA baseline survey in breeder pigs, 2008. Weaner-to-finish and finisher holdings are not covered by the survey (EFSA, 2009a)[11]

The gains from controlling *Salmonella* in pig meat alone might be lower compared to controlling *Salmonella* all along the food chain, i.e. pre-harvest and post-harvest.

11 Please refer to Glossary at end of report for definitions.

1.1. Interpretation of the terms of reference

The current opinion is based on the QMRA consortium's report, findings in previous EFSA/EU opinions, other risk assessments, the scientific literature, and expert opinions.

In this opinion slaughter pigs are synonymous with fattening pigs, and breeder pigs with breeding pigs. Furthermore, the terms *Salmonella* "serovars" and "serotypes" are used synonymously in this opinion.

The issue of antimicrobial resistance in *Salmonella* was not dealt with in this opinion, as it was outside the terms of reference (TOR).

It should be noted that lymph node prevalence of *Salmonella* does not tell the same story as prevalence of antibodies to *Salmonella*. Lymph node prevalence represents the current status of infection amongst pigs while prevalence of antibodies (serology) represents the history of infections amongst pigs.

The focus of this opinion is on the incidence of human *Salmonella* infections. Other health parameters such as disease burden (disability adjusted life years - DALY) and mortality are assumed to be proportional to the incidence. Therefore the public health risk is measured as the number of *Salmonella* cases and relative changes in such number. This assumption seems reasonable and is supported by findings of Haagsma *et al.* (2008).

In this opinion it is assumed that all relevant EU legislation for animal health, welfare and food safety are complied with. This opinion does not consider the economical benefits and costs as they are outside the EFSA remit and are considered separately, as the DG Health and Consumers has commissioned a benefit cost analysis.

The QMRA model did not consider the effect of trade of pig meat, pig meat products and live pigs within the EU or with third countries.

1.2. Roles of QMRA consortium, BIOHAZ Panel and WG, and the benefit cost analysis contractor

EFSA received the request from the European Commission (EC) to carry out a quantitative risk assessment on *Salmonella* in breeder and slaughter pigs. The task was given to EFSA's Scientific Panel on Biological Hazards.

A working group (WG) was established to draft the scientific opinion for consideration by the Biological Hazards Panel. In order to support the WG, an Article 36 call was launched and this led to the grant being awarded to a consortium (VLA, RIVM, Food-DTU), hereafter referred to as the QMRA consortium.

The QMRA consortium's task was to carry out a quantitative microbial risk assessment as specified in the grant agreement based on the results of the baseline studies of slaughter and breeder pigs.

In addition, DG Health and Consumers has commissioned a benefit cost analysis of possible control measures in the pig meat food chain as a separate exercise to be undertaken by another contractor.

Due to delays in completing the baseline study on *Salmonella* in breeder pigs it has been necessary to work in parallel instead of sequentially. Therefore with a view to facilitate the work progress and respect the deadlines there has been an open exchange of information between those doing baseline studies, the EC representatives, EFSA secretariat, Panel on Biological Hazards and its working group, the QMRA consortium, and the EC contractor doing the benefit cost analysis.

2. General consideration on *Salmonella* and salmonellosis

2.1. *Salmonella* infections in humans

Salmonella infections in humans may result in distinct clinical syndromes, including acute gastroenteritis, fever, and bacteraemia with or without focal extra-intestinal infections and reactive arthritis (Cohen *et al.*, 1987). Haagsma *et al.* (2008) investigated the disease burden of salmonellosis in the Netherlands, of which 697, 17 and 33 Disability Adjusted Life Years (DALYs) were attributed to gastrointestinal disease, reactive arthritis and inflammatory bowel syndrome, respectively. The corresponding number of cases of gastrointestinal disease, reactive arthritis and inflammatory bowel disease was 35,400, 460 and 7 cases, respectively.

In line with previous EFSA opinions all *Salmonella* serovars are considered as representing a potential public health hazard. Currently there is no way of predicting in the laboratory whether a *Salmonella* serovar represents a public health hazard or not. Nevertheless, there is evidence that some *Salmonella* serovars are more invasive (Wollin, 2007) and that some are more persistent throughout the food chain. The frequency rankings of *Salmonella* serovars found in feed, live pigs, pig carcasses and humans are not the same. This could reflect the possibility that different serovars have a different virulence or different ability to survive and multiply along the food chain. There is a need to develop science-based criteria before attempting to differentiate between *Salmonella* serovars.

When more knowledge of differences in virulence of *Salmonella* serovars and their ability to survive and multiply in the food chain is available, possibilities for further refinements of the current model will arise.

2.2. Slaughter of *Salmonella* infected pigs and impact on human health

Finisher pigs may harbour *Salmonella* in several tissues, especially the digestive tract including associated lymph nodes and also on the contaminated skin. Subclinically infected carriers may be a risk factor for horizontal transmission via contaminated faeces, e.g. during transportation to the abattoir or while waiting in the lairage before slaughter (Vieira-Pinto *et al.*, 2005). Several studies have attributed stress factors induced by transport and feed withdrawal to an increased shedding of *Salmonella* from *Salmonella*-infected pigs (Isaacson *et al.*, 1999; Morgan *et al.*, 1987). A translocation of *Salmonella* to muscular tissue was observed in slaughtered pigs after exposure to severe stress (Fehlhaber, 2003; Fehlhaber and Alter, 1999). On the other hand, according to other experimental studies, transportation of pigs had no influence on the distribution patterns and numbers of *Salmonella* Typhimurium in organs or faecal samples in infected pigs (Marg *et al.*, 2001; Scherer *et al.*, 2008). The role of sub-clinically infected pigs for horizontal transmission via contaminated faeces during transportation to the abattoir or while waiting in the lairage is highlighted in all these studies. Variations in the number of *Salmonella* carriers related to the transport stress may be explained by differences in the experimental design applied for the study (e.g. number of pigs examined, use of *Salmonella* strain, transport time and conditions).

At slaughter the tonsils are frequently found to contain high numbers of *S*. Typhimurium and may play an important role in the invasion and dissemination of *Salmonella* (Fedorka-Cray *et al.*, 1994). A significant correlation was observed between prevalence of *Salmonella* in the tonsils and positive carcasses during slaughter (Swanenburg *et al.*, 1999). In a longitudinal study on experimental infection with *S*. Typhimurium definitive phage type (DT) 104 in fattening pigs, the highest level of *Salmonella* colonisation was detected in tonsils, jejunal and ileocaecal lymph nodes at slaughter (Scherer *et al.*, 2008). The presence of *S*. Typhimurium in mandibular lymph nodes may also pose a risk of cross-contamination due to incision during sanitary inspection and processing. Once a processing line is contaminated, *Salmonella* can be isolated from the machinery, hands of workers, knives and carcasses (Berends *et al.*, 1996; Small *et al.*, 2006).

From 1990 to around 2000, the multiresistant *S.* Typhimurium DT 104 was, in some MSs, one of the most frequently isolated serotypes from pig meat (Poppe *et al.*, 2002) which does not usually cause

clinical disease in pigs (van der Wolf *et al.*, 1999). Nevertheless, sub-clinically infected carriers pose a reservoir of infection that is of considerable importance in human health (Olsen *et al.*, 2001).

2.3. Pathogenesis and dynamics of *Salmonella* infection in pigs

Results of clinical studies in pigs demonstrate that *S.* Choleraesuis infection can result in septicaemia and to enterocolitis, pneumonia and/or hepatitis as a consequence of bacteremia whereas infection with *S.* Typhimurium may sometimes cause enterocolitis and diarrhoea (Reed *et al.*, 1986; Schwartz, 1999; Wood and Rose, 1992). Other experimental investigations in weaning piglets using an oral dose of 10^9 colony-forming units (cfu) *S.* Typhimurium led to clinical signs such as fever and vomiting at the early stage of infection (Scherer *et al.*, 2008; Szabo *et al.*, 2009) but also the absence of clinical signs (Kampelmacher *et al.*, 1969).

Differences in the clinical outcome after exposure may be due to serovar or strain specific differences (Huehn *et al.*, 2009) in virulence and/or constitution of pigs such as susceptibility and predisposition. In two studies (Osterberg *et al.*, 2009; Osterberg and Wallgren, 2008) pigs were inoculated with the following serovars: Typhimurium, Derby, Yoruba or Cubana, at doses of $0.65*10^9$, 10^6 and 10^3 cfu, respectively. The results indicated large differences in serological responses and the status of *Salmonella* infection. Both serovar and number of *Salmonella* inoculated were considered to be important factors.

Following *Salmonella* infection in pigs, pathogenesis is characterized by three phases: (1) colonisation of intestines, (2) invasion of enterocytes, and (3) bacterial dissemination to lymph nodes and organs (Berends *et al.*, 1996). Some *Salmonella* serovars are able to invade the tonsils 30 minutes after oral uptake/contact with the contamination source and within few hours (2h to 3h) they can colonize the mandibular lymph nodes, colon, caecum, and ileocaecal lymph nodes (Hurd *et al.*, 2001a). After experimental infection with *Salmonella* Typhimurium DT104, pigs excreted *Salmonella* during two weeks post infection, thereafter shedding rate in faeces declined and became intermittent until the end of the five months fattening period (Scherer *et al.*, 2008). Several organs including the tonsils serve as important sites for persistence of *Salmonella* (Fedorka-Cray *et al.*, 1994; Loynachan *et al.*, 2004). Since *Salmonella* is able to survive and proliferate in phagocytes and leucocytes, translocation to gut associated lymphoid tissue is possible (Reed *et al.*, 1986; Wells, 1990).

The immune response in the intestine of the host is determined by a number of complex mechanisms including factors such as immune cell interactions with bacteria and their products (Bailey *et al.*, 2001). In several studies with pigs challenged with *Salmonella*, the development of the humoral immune response in serum was investigated. After experimental infection with *S.* Typhimurium DT 104, *Salmonella*-specific IgG antibodies are detected in the majority of pig sera between day 22 and 39 post infection (Szabo *et al.*, 2008).

Most publications on pathogenesis in pigs are on serovars known to be pathogenic to pigs, like *S.* Choleraesuis, while for outbreaks (human cases) attributed to pig meat the serovar Typhimurium is most frequently isolated. Generalizing from data based on outbreaks of *S.* Typhimurium may lead to a biased estimation of human health risk (overestimation), since *S.* Typhimurium and in particular, the outbreak isolates, are thought to be more virulent (see discussion in section 5.3.6).

2.4. Diagnostic aspects (bacteriology, serology)

In an earlier EFSA opinion (EFSA, 2006), the principles, advantages, disadvantages, and relevance of bacteriological and immunological analysis methods have been described. The objectives of the two approaches are very different and the choice of diagnostic method to be used will depend on the actual situation and the questions that are required to be answered.

The actual presence of *Salmonella* in pigs can be directly diagnosed at the abattoir or at the farm level by isolating *Salmonella* with various established bacteriological methods (Christensen *et al.*, 2002). Since conventional culture methods are laborious, time consuming and costly, serological techniques

using ELISA based on lipopolysaccharide antigens have proven to be practical and cost effective methods and therefore more suitable for routine testing of herd status at slaughter (Nielsen *et al.*, 1995; Proux *et al.*, 2000). Serological methods indicate previous exposure to *Salmonella* but cannot differentiate between acute or chronic/sub-clinical infection of an individual pig or if sero-positive pigs are currently carrying or shedding *Salmonella* or have eliminated the infection. Recently-infected pigs are also not identified before seroconversion. Therefore, serological testing is less suitable for individual animals but appropriate for screening purposes at herd level (Nollet *et al.*, 2005; Wong *et al.*, 2003).

The monitoring systems applied in *Salmonella* surveillance programs for fattening pigs are usually based on serological examination by means of ELISA. The results are often used to classify herds into e.g. three categories, herds with low, moderate or high prevalence of antibody-positive pigs (Mousing *et al.*, 1997). The criteria for the classification rules (risk farm versus non or low risk farm) as well as the sampling schemes can differ significantly between MSs.

Following infection with *Salmonella*, there is a high faecal excretion in pigs within two weeks post infection and the peak of bacterial excretion in faeces is followed by an immune response after a further 1-2 weeks (Nielsen *et al.*, 1995). Thus, when pig sera are tested for specific antibodies in the early stage of infection, negative results can occur due to delayed seroconversion. Conversely, during the chronic stage of infection which covers the main part of the life span of a fattening pig, animals show a higher rate of sero-positive animals compared to a lower rate of pigs shedding *Salmonella* in faeces (Scherer *et al.*, 2008).

The introduction of *Salmonella*-infected pigs (e.g. gilts or boars for breeding herds, piglets for grow-to-finishing farms) is an important external source. However the challenge to implement control measures is to ensure that incoming pigs are *Salmonella*-free. The reliable detection of infected pigs (individual level or group/herd level) by the use of bacteriological methods remains laborious and is time consuming. Available methods, when not used in repeated testing, have a low sensitivity when used on individual animals, but are more appropriate when used on a herd or group level/herd of origin. The sole use of serology is not accurate and other tests (e.g., on faeces) are needed (Davies *et al.*, 2003). However judicious use of testing at herd level over extended periods (months, years) combined with knowledge about biosecurity level in the herd and its disease history might allow conclusions about the *Salmonella* status of pigs.

Quality assurance has to be applied in order to produce results that can be compared with confidence between laboratories/countries. Results obtained using bacteriological methods and immunological methods cannot be compared directly. Since the same laboratory was analysing results from baseline studies of breeder pigs and slaughter pigs, it is possible that a part of the correlation observed between slaughter pig and breeder pig prevalence in a MS may be attributable to the sampling and processing of samples in the national laboratory. The magnitude of this effect cannot be assessed at this point in time. The purpose of the design of baseline surveys was to minimize this sort of correlation.

In conclusion, it is important to consider the dynamics of *Salmonella* infections in pigs and the characteristics and objectives of bacteriological and/or serological tests, when designing surveillance or monitoring programs, e.g. baseline studies, and interpreting the results of these.

3. Review of relevant risk assessments, sources attribution, intervention studies, and EFSA opinions

3.1. Risk assessments

Human health is usually the end-point of zoonotic microbiological risk assessments, as food safety and public health protection are the overall objectives of microbiological risk analysis (Codex Alimentarius, 1999).

Quantitative risk assessments concerning the whole food chain or part(s) of it have typically been modelled as modules, following the approach developed for QMRAs on *Salmonella* in poultry (FAO/WHO, 2002; USDA, 1998). In the modular approach, the results of one module are exploited as inputs in the following module. Both deterministic and stochastic methods have been used.

Only a few farm-to-fork QMRAs have been published on *Salmonella* in pig meat production. As with all risk assessments, they have also been targeted at addressing risk management issue(s) and may therefore be limited from other points of view (Bollaerts *et al.*, 2009).

In Belgium, a QMRA model called METZOON assessed the risk on human salmonellosis through household consumption of fresh minced Belgian pig meat, both pure and mixed with other meat. This assessment started from primary production (fattening herds) and ended at the point of human illness (Bollaerts *et al.*, 2009). It used the dose-illness model that was fitted by Bollaerts *et al.*, (2008) to outbreak data of human salmonellosis taking into account host susceptibility (susceptible versus normal population), serovar and food matrix. The authors included this information into the farm-to-fork risk assessment in order to estimate the annual number of *Salmonella* cases. The human cases were estimated mainly to be a consequence of undercooking and to a lesser extent, cross-contamination in the kitchen.

Delhalle *et al.* (2008) evaluated the potential risk factors of *Salmonella* contamination of pig carcasses associated with production parameters, technical facilities and methods used for cleaning/disinfection in the ten largest Belgian slaughterhouses. The study indicated that working practices such as scalding with steam, a second flaming after polishing, and cleaning/disinfection of the splitter machine several times a day, were beneficial in reducing contamination by *Salmonella*.

Production stages after the slaughterhouse were also studied in seven cutting plants, four minced meat plants of the four largest retailers in Belgium using data from the official Food Agency as well as from self-monitoring (auto-control) programs (Delhalle *et al.*, 2009a). Another Belgian QMRA on human salmonellosis following consumption of fresh minced pig meat was conducted by Delhalle *et al.* (2009b). Its main goal was to give practical options to reduce effectively the risk of human salmonellosis through the consumption of minced pig meat.

In Finland, Ranta *et al.*, (2004) assessed the consumer risk due to all pig meat-derived foods available to consumers and *Salmonella* prevalence in the pig meat food chain from slaughter pigs to consumption in order to evaluate the efficacy and economics of the national *Salmonella* control programme, as well as the influence of special guarantees[12] on consumer risk.

In the UK, consumer risk regarding *S.* Typhimurium acquired from pig meat, mixed meat products and bacon was also assessed with a farm to fork model by Hill *et al.* (2003).

In Denmark, Alban *et al.* (2002) compared the number of portions consumed and salmonellosis risk to consumers acquired from dry-cured sausages produced from domestic and imported pig meat, and reported that the imported sausages were contaminated more than 37 times more often compared to domestic sausages. According to the Finnish QMRA, imported pig meat and pig meat-derived foods caused as many salmonellosis cases as domestic products, although imports accounted for only 8% of the overall consumption (Ranta *et al.*, 2004). The consumer risk due to *Salmonella*-contaminated pig meat products was assessed in the Abruzzi region of Italy, revealing fresh pig meat to be an important source of human salmonellosis (Giovannini *et al.*, 2004). The study revealed that the *Salmonella* prevalence in fresh sausages was significantly higher than in fresh meat, indicating contamination during preparation or bacterial growth during the manufacture and/or storage of sausages.

12 Special guarantees ('additional guarantees' until 31.12.2005) concerning certain animal-derived food products including fresh and minced meat from porcine animals were admitted to Finland and Sweden at the time of their accession to the European Union (Council Directive 94/65/EC; Council Decision 95/409/EC; Commission Regulation (EC) No 1688/2005) because of their low *Salmonella* prevalence and ongoing national *Salmonella* programmes. According to the regulation, all such consignments have to be tested *Salmonella*-negative before exported them to these countries.

3.2. Source attributions

In Denmark, domestically produced pig meat was estimated to be the most important source of human salmonellosis in 2008 (9%), followed by imported chicken (5%) and table eggs (3%). The estimated number of cases attributed to the consumption of pig meat increased three-fold compared to 2007 (Anonymous, 2009). This increase is partly explained by the occurrence of an unusual number of pig meat-related outbreaks in 2008 (Ethelberg *et al.*, 2008). In recent attribution studies done by Pires *et al.* (Pires, 2009; Pires *et al.*, 2008) the proportion of pig meat-associated cases acquired domestically was estimated for four EU countries: Denmark (3.6-9.7%), the Netherlands (7.6-15.2%), Sweden (0.1-0.3%) and UK (3.4-3.7%).

In Finland, a model based on a similar type of comparison and initially developed for the estimation of salmonellosis cases due to broiler meat (Maijala *et al.*, 2005) was incorporated in the QMRA on *Salmonella* in the pig meat production chain (Ranta *et al.*, 2004). When compared to other *Salmonella* QMRAs, conducted at the same time for broiler, egg and beef production chains, it appeared that pig meat and pig meat-derived foods were the second largest group of food products causing salmonellosis in consumers in Finland, while beef and beef-derived foods were the most important.

3.3. Intervention studies

Most risk assessments of the effect of different risk management options do not focus on the whole production chain but instead concentrate on certain stages of the food chain and more closely investigate interventions or processing techniques used. Assessments on the effect of different risk management options have been conducted at various levels of the food production chain. A low prevalence of *Salmonella* in the raw material, improvements in singeing efficiency, and a reduction of cross-contamination during degutting and handling at slaughter were considered as important risk-reduction factors in the slaughter process (Alban and Stark, 2005). The results of the Belgian QMRA showed *Salmonella* reduction during polishing, evisceration and chilling would be the most effective strategies of the slaughter process while processes at the beginning of the slaughter process seem to have only a limited effect (Bollaerts *et al.*, 2010).

The implementation of good hygiene practices (GHP) from the transport phase up to the cutting or retail phase coupled with a decontamination step at the end of the slaughter line, might reduce the prevalence of contaminated carcasses and pig meat by as much as 50-60% (Berends *et al.*, 1998a). Monitoring of critical points, the condition and cleanliness of equipment, good slaughtering practices, and effective cleaning and disinfection of equipment were considered as the key elements contributing to food safety during the slaughter process (Delhalle *et al.*, 2008).

In meat cutting plants and butchers' shops, improper cleaning and disinfection, manipulation of contaminated materials and (re)contaminated surfaces were evaluated as the most important risk factors, however implementation of GHP did not reduce daily cross-contamination by more than about 10% (Berends *et al.*, 1998b). In addition, GHP in abattoirs and meat cutting plants was also considered to have only marginal effects on the occurrence of *Salmonella* in final products, according to the studies of Gonzales Barron *et al.*(2009). In that study final rinsing and chilling of carcasses was found to have a considerable influence.

According to some risk assessments, the most effective measures to reduce the consumer risk take place at slaughterhouse level and can be implemented by means of decontamination procedures (Berends *et al.*, 1998b; Bollaerts *et al.*, 2010; Hurd *et al.*, 2008; Sommer *et al.*, 2003).

In some countries with low *Salmonella* prevalence, such as Finland, Norway and Sweden, the application of pre-harvest control measures has been an essential part of their *Salmonella* control programmes, and is regarded as the major reason for their low prevalence status both at the pre-harvest and post-harvest level including pig meat (Hopp *et al.*, 1999). An analysis of the pre-harvest focus and

the non acceptance of *Salmonella*[13] as applied in Sweden has demonstrated its advantages in public health terms, in relation to a more conservative approach (Engvall A., 1993). The Finnish cost-benefit analysis, based on the *Salmonella* QMRA conducted, gave similar results (Kangas *et al.*, 2007).

The calculations based on the Finnish risk assessments on poultry, beef, table egg and pig meat production chains suggest that controls in primary production play the major role in *Salmonella* risk caused to the consumer.

In general, the conclusions from risk assessments will be determined by the local conditions (current prevalences), objectives of the assessment, model/study design and the input data used.

3.4. EFSA opinions

The Biological Hazards Panel has already adopted an opinion on risk mitigation options for *Salmonella* in pig production (EFSA, 2006). The conclusions of this opinion remain valid in general.

Furthermore, the Panel adopted an opinion on source attribution for human salmonellosis from meat (EFSA, 2008a).

4. Summary of Consortium Report

Under Article 36 of the European Parliament and Council Regulation (EC) No 178/2002 (EC, 2002), the European Food Safety Authority (EFSA) published a call for a "Quantitative Microbiological Risk Assessment (QMRA) on *Salmonella* in slaughter and breeder pigs".

As a consequence of the objectives provided in this call the VLA/RIVM/Food-DTU consortium have worked towards a full farm-to-consumption QMRA. After slaughter and dressing, the QMRA focuses on three different products: pork cuts, minced meat and fermented sausages. At every stage possible the opportunity of cross-contamination is considered. To describe the cross-contamination the model needed to be highly mechanistic, which although it leads to a more complex model will allow a better examination of interventions for *Salmonella* in pigs.

The aims of the QMRA were to assess:

- the expected reduction of *Salmonella* cases in humans (or pig meat at retail) by a reduction (e.g. 5- or 10-fold) of *Salmonella* prevalence in slaughter pigs (based on bacteriology or serology at slaughter);
- the sources of infection for fattening pigs at farm level;
- the reduction of the prevalence in slaughter pigs by the most important potential treatments or control measures at farm level;
- the impact of transport, lairage and slaughter processes on contamination of carcasses;
- the expected reduction of *Salmonella* cases in humans (or pig meat) by the most important control measures during transport, at lairage or during the slaughter process.

The full report is published on EFSA's website[14].

13 The non acceptance strategy means that corrective actions should always be taken whenever *Salmonella* is found in the food chain.

14 www.efsa.europa.eu/en/scdocs/scdoc/46e.htm

5. Review of modelling choices, assumptions and data gaps

5.1. General remarks

The consortium's discussion on the data gaps and assumptions used within the model can be found in the QMRA report chapter 15.3. A summary of the technical model appears in Appendix B to this opinion.

In the probabilistic risk assessment approach, a first step is to identify the variables of interest and to assign a probability distribution to each (Hamed and Bedient, 1997). The probability distributions for the variables are often selected in an empirical way (Hattis and Burmaster, 1994). The degree of confidence in the final QMRA outputs will depend on the way the variability, uncertainty and assumptions are handled at the different risk assessment steps.

The assessment of possible options for control measures has to consider that in the pre-harvest phase the occurrence and spread of *Salmonella* is the result of infected pigs, while during the harvest and post-harvest phase the occurrence and spread of *Salmonella* is the result of the influence of cross contamination and pathogen growth/reduction or dissemination that might occur at different links of the food chain.

During the pre-harvest phase of the pig meat production, there are in principle three main sources of *Salmonella* introduction in slaughter pig farms. One is ingestion of contaminated feed, the other is exposure to *Salmonella* shed by *Salmonella*-infected pigs along the breeding pyramid and the third is exposure to *Salmonella* from other sources of the environment (EFSA, 2006).

During the harvest and post-harvest phases of the food chain the main route of transmission of *Salmonella* is cross-contamination from the carcasses of the primarily infected slaughter pigs.

The QMRA assumed that all *Salmonella* serovars equally represent a potential public health risk as requested in the terms of reference without any attempt at differentiating them. In a similar way, the assumption of similar probability of pigs acquiring *Salmonella* infection from an exposure regardless of serovar was applied. However Osterberg *et al* (Osterberg *et al.*, 2009; Osterberg and Wallgren, 2008) found that the dose-response in newly weaned pigs exposed to *Salmonella* may vary considerably between serovars.

5.2. Impact of modelling choices and assumptions

According to the Codex Alimentarius Commission (1999) a QMRA should include four steps: hazard identification, exposure assessment, hazard characterization and risk characterisation. Originally, risk assessment techniques evolved from toxicological risk assessment (estimation of No Observed Adverse Effect, Acceptable Daily intake and Tolerable Daily intake). Microbial risk assessments are different as the amount of exposure to microbial pathogens is much harder to quantify as a result of potential microbial growth and inactivation. In addition, and in particular for *Salmonella*, host behaviour and host resistance (immunity) strongly interacts with the final risk. This is what makes QMRA of infectious diseases very complex.

In the QMRA, presented by the consortium, a probabilistic modular risk model (Modular Process Risk Model, or MPRM) as proposed by Nauta *et al.* (2005) was developed, in which the food production pathway for pig meat is split up in consecutive modules (farm, transport & lairage, slaughterhouse, cutting plant, preparation plus consumption & dose response module) with the output of one module serving as input for the next module. This approach allows and facilitates building pathogen transmission models, evaluation of changes and variability in prevalence and bacteriological concentrations. In addition, in a MPRM, intervention analysis is possible (and subsequently cost-benefit analysis) as changes in prevalence, concentration of *Salmonella* and unit size can be modelled by means of the basic processes in microbial (growth and inactivation) and food/carcass/pig meat handling processes (cross contamination, cutting, partitioning and mixing).

In the following those modelling choices (methodologies) and assumptions that may influence the outcome/output of the QMRA will be discussed and are important issues will be highlighted that should always be kept in mind, when analysing and using the results of the QMRA and deriving related conclusions from them.

5.2.1. Cluster analysis – definition of EU regions and selection of representative MSs within each region.

Four countries (MS1-MS4) were selected as cases to capture the variability in the EU wide situation. The selection was based on a cluster analysis, (determining clusters of countries with similarities in pig production and slaughter data) using objective criteria (ratio big/small holdings, ratio output form big/small slaughterhouses, pig meat consumed and relative consumption of sausages) where the weight of consumption was double compared to the other criteria. The methodology for the cluster analysis (k-means clustering) is very good and intended for situations in which all the variables are of the quantitative type. The k-means clustering (hard clustering methods) will, inevitably, lead to misclassifications and this is especially true for MSs near the boundaries. Therefore, different initial partitions can result in different final clusters. Other variables that could not be included, due to lack of data, could have resulted in another classification.

The inclusion of the data on prevalence of infected carcasses and/or lymph nodes (input farm module) from the baseline studies (slaughter pigs and breeder pigs) was excluded by the consortium because that data was intended for validation of the model. Inclusion of baseline data was found not to have a large bearing on the result of the clustering.

For these reasons, one should be careful with the interpretation of the model output for each MS separately. This is particularly important if e.g., this clustering is used in order to set targets for prevalence reduction. Hence, setting *Salmonella* prevalence targets based on this clustering is neither recommended nor intended.

5.2.2. Parameterisation for the different modules (farm – transport & lairage – slaughterhouse – preparation & consumption)

In each module, parameter estimation was done by using data, if these were available. Significant data gaps were identified for some case study MSs. Therefore, input parameters (distributions) from other countries were used and these estimates were kept identical for the others. This approach might introduce a bias for some MSs classified in one of the four clusters. This was especially important for the farm module, which served as input for the subsequent modules in the modular QMRA. In the farm module the estimates for large farm/small farm management parameters, those for the sources of infection for *Salmonella* as well as the parameters used in the transmission model were derived from limited sources (main sources used are from one MS only (MS2)) and/or assumed.

Throughout the model, some distributions were assumed and/or derived from expert opinion. In this case it would be more precise to include uncertainty in the defined distributions as neglecting the uncertainty around a variable parameter might result in a 'too precise' output for some MSs and makes extrapolation and generalisation difficult. This is especially relevant for risk managers during target setting and/or recommendations for *Salmonella* reduction at the different stages along the pig meat production chain. For the transport module it is clear that reducing stress (time of transport and stocking density) would significantly lead to a lower prevalence of excreting and/or contaminated pigs. These issues are addressed in the uncertainty analysis (QMRA report chapter 15).

In the slaughterhouse module, considerable efforts were made to model the cross-contamination down to the last detail. Due to the complexity of this module, several (hidden) assumptions had to be made and the quantitative impact of specific assumptions is not always obvious. For this module, the same caution must be taken regarding the parameterisation, as estimates were derived from limited sources and or derived from 'other than *Salmonella'* parameters (e.g. use of the increase in *Enterobacteriaceae* during polishing and transfer (transmission) parameters obtained from chicken for the belly opening

phase in the slaughterhouse). In addition, the estimates for the parameters for small slaughterhouses are derived from one small slaughterhouse in the Netherlands and the used parameterisations may lead to biased results for those countries having many small slaughterhouses with a different prevalence as input for the slaughterhouse module. Some of these issues are addressed in the uncertainty analysis (QMRA report chapter 15).

Within the slaughterhouse module, the cross contamination - the contamination of a carcass (or other unit under investigation) by means of a second agent (e.g. a cutting knife, or the scalding tank), which has previously been contaminated by another carcass, is modeled and assumed to take place in discrete time. At these different slaughterhouse stages, machinery parameters are modeled using data from scientific literature. It is clear however, that the slaughterhouse environment varies throughout the EU and within slaughter stages and that specific equipment and settings of the machinery is not constant as such. Therefore, the variability and the uncertainty in the outcome of the slaughterhouse module is expected to be much larger and subsequently impact of the estimated number of human cases.

The meat product selection (pig meat cuts, minced meat and fermented sausages) and modelling the cross-contamination transfer parameters during the consumer and preparation phase is based on the existing diversity and their differences in risk in the harvest and post-harvest processing stages. Again, some parameters were derived from a few limited sources and may not be applicable in all MSs.

5.2.3. Sensitivity Analysis and Uncertainty Analysis

A sensitivity analysis is performed to assess how the variation of the output is affected by changes in the model inputs. The sensitivity analysis was conducted by a one-way analysis of variance (ANOVA) test. In contrast, the uncertainty associated with the parameter values was investigated in the uncertainty analysis. This ANOVA tests the parameters of the model that incorporate variability - the parameterized estimates, by using a statistical distribution to describe the variability against a response variable and only considers the variability of the parameter values which are part of the baseline model. In the QMRA model, an independent sensitivity analysis for the farm, transport, lairage, slaughterhouse, cutting plant and one for each product type during the preparation and consumption module was performed. The dose-response module was not considered for sensitivity analysis.

Therefore, the results of the sensitivity analysis should only be interpreted as a 'one-to-one' relationship which means that those parameters that were found to important in the sensitivity analysis (e.g. within-batch prevalence, probability of pigs being stressed during transport, minced meat storage time in fridge and probability of pigs being stressed during transport) are important only for the module in which they were implemented.

Depending on the scope and the desired level for uncertainty assessment in a QMRA process, a tiered approach (Tier 1, 2 and 3) is recommended by EFSA (2006) and FAO/WHO (2008). The tier level should be proportionate to the needs of the QMRA model in order to effectively respond to the risk management questions. Tier 1 analysis starts by treating all uncertainties qualitatively and is the simplest form of uncertainty analysis. Tier 2 and Tier 3 are quantitative uncertainty assessment approaches. Tier 2 consists of the deterministic analysis of uncertainties. Different alternative point estimates are filled in for uncertain inputs in the assessment and their impact on the assessment outcome is calculated. The most detailed level and resource intensive type of uncertainty analysis is obtained via a probabilistic analysis of uncertainties (Tier 3).

In this QMRA model the uncertainty associated with the parameter values was analyzed by changing certain parameters to a minimum and a maximum value. The choice of the parameters and the alternative values was done in a subjective way and the resulting probability of illness (for the three products) was compared with the baseline results. Therefore, the result may be biased and, in some cases, unrealistic. In addition, the uncertainty analysis did not allow a distinction between the variability and uncertainty and how this propagates through the model (second order distributions). By identifying qualitatively, deterministically or probabilistically uncertainties and separately from variability, information on data gaps can be obtained. In order to take decisions, risk managers can ask

for additional data collection to reduce uncertainties that are policy-relevant. These issues are highlighted in the QMRA report.

5.2.4. Intervention analysis

In order to investigate the effect of reducing slaughter pig prevalence, breeding herd prevalence and carcass contamination on the number of human salmonellosis, a number of hypothetical and specific control measures were investigated. This methodology is straightforward and the results are of interest to policy makers (target setting) and risk managers.

It should be clear that the effect of these control measures will always be overestimated as it is assumed that the uptake of each intervention is perfect across all stages of the pig meat production and across the MSs and that each control measure would be implemented in such a way to produce the effect desired. Subsequently, control measures for which it is obvious that there is little or no gain to be expected might be excluded for target setting.

5.3. Data gaps and assumptions

5.3.1. The pre-harvest farm stage

The occurrence of *Salmonella* at this stage of the pig meat food chain has been subject to a considerable number of studies. Studies on pre-harvest control of *Salmonella* are few and usually have a different focus and are of different quality than what is needed for the purpose of this opinion. Therefore large amounts of information are available but the quality of the studies is variable. Even though results of different control measures can be obtained also from *Salmonella* in other animal species than pigs and also from other microbial infections, more data is required specifically for the result of control measures against *Salmonella* in different types of pig herds and different epidemiological situations.

One critical simplification regarding the pig dose-response function is differentiating between those pigs fed wet or dry feed only. The two dose-response functions (for wet and dry feed) are assumed to be applicable to all ages of pigs. However, pigs will be exposed to different levels of *Salmonella* depending on the farm type.

Another simplification is the assumption that the probability of a breeding herds being infected is represented by national prevalence of breeder herds as a single number. In a MS with a certain mean prevalence of *Salmonella* infected breeder herds, some groups of herds might have a higher prevalence while others have a lower and can also be free from *Salmonella*. The need for, and the result of, different control measures are therefore not equal for all herds in a MS.

The QMRA consortium's report has identified the impact and the relative importance of control measures at different levels of the food chain. The assessments of risk reductions due to different control measures do not take into account the time needed to achieve full implementation of such control measures. For example, control measures for breeder pigs might reach their optimal effect after 5-10 years while the QMRA model is simulated for a period of 500 days, and assuming immediate and full implementation.

5.3.2. Transport and lairage

The issue of transport relates to pig supply i.e. piglets or replacement stock depending on the type of farm. Truck cleaning and disinfection routines are still perceived as laborious tasks and may sometimes be disregarded. Modelling this lack of compliance may not be straightforward. Hence, it is assumed in this opinion that all EU regulations are complied with.

Despite cleaning and disinfection efforts, residual *Salmonella* contamination can occur (Mannion *et al.*, 2008). Data published on the proportion of pigs being transported to slaughter and between farms

at national level are scarce in the EU. Among the questions raised are those of farming and transport conditions that can vary considerably within the EU and even within the MSs.

Within the QMRA model, transport is modelled between farms for weaning and growing stages only, and at slaughter.

5.3.3. The slaughterhouse

Two types of slaughterhouses were considered in the QMRA: large and small. The uncertainty about the model framework is higher for small slaughterhouses than for the large ones. The variability between MSs is probably larger for small slaughterhouse. In addition there is a lack of data for both types to estimate all model parameters.

The slaughter process can be divided into multiple steps, each corresponding to a specific operation on the pig and further, on the carcass.

A survey was carried out in Belgium in the ten largest pig slaughterhouses of the country. A high variability was found between slaughterhouses concerning *Salmonella* contamination of pig carcasses after chilling with prevalence ranging from 2.6% to 34% (Delhalle *et al.*, 2008).

Rossel *et al.* (2009) found out that carcass contamination was directly linked to the skin contamination of live pigs before stunning. The conditional probability of carcass surface contamination decreased from 59% to 35% when the skin was contaminated or not. On the other hand, skin contamination was connected to the contamination of lairage pens. The conditional probability of skin contamination decreased from 70% to 36% when the floor of the lairage pens was contaminated or not. The authors also showed that the pigs unloaded in lairage pens previously occupied by subsequent batches during the working day were more exposed to skin contamination when compared to pigs unloaded in lairage pens at the end of the working day, but after the pens had been cleaned. The authors did not report on the hygiene routines performed in the lairage.

Stunning-bleeding and scalding are also important steps in relation to *Salmonella* contamination. CO_2 stunning can lead to release of faeces so that pigs can be rather dirty after stunning, however the impact of the stunning method with regard to skin contamination by *Salmonella* is not known. This can partially explain the slaughterhouse effect often observed. It may also interfere with "country influence", depending on the proportion of slaughterhouses using such equipment. The cleanliness/dirtiness of the pigs entering the scalding tank determines the extent of contamination of the water in the tank, while the maintenance of a high temperature of the water will reduce the *Salmonella* burden.

The time spent in the tank is variable from one slaughterhouse to the next, as well as water temperature, and the latter can even vary to some extent during the day in a given operation. Experimental data that could help establishing equations about contamination/decontamination of the skin of the pigs within the scalding tank are missing. Such data were recently published about pneumotropic bacteria (Marois *et al.*, 2008). The findings demonstrated that *P. multocida* could be isolated from the water, and that contaminated water could reach the lower part of the lungs. There seems to be a general positive relationship between skin contamination before slaughter (after lairage) and external carcass contamination at the end of slaughter line (Rossel, 2009). Therefore cleanliness of the pigs at the early step of the slaughter process is worth considering. Since it can hardly be evaluated in a direct way, an indirect estimation might be assessed, e.g. through the equipment in place and their functioning.

Another group of factors that can interfere with carcass contamination relates to the equipment of the slaughterhouse and the aerosols which are produced when the slaughter line is running. In the preliminary report, the consortium uses the term "house flora" to designate those factors. The different steps are explained and the authors mention some possible circumstances not explicitly accounted for in their model (e.g. dripping of condensed water, formation of a protective biofilm on the machinery such as knives etc). Cross-contamination between adjacent carcasses is possible through direct contact

or airborne contamination. To date, little interest has been given to airborne transmission of bacteria within the slaughterhouse, a situation rather contrasting with the high number of papers published about airborne transmission of bacteria between live pigs, including *Salmonella enterica* (Dee *et al.*, 2009; Proux *et al.*, 2001). Moreover, equipment-mediated contamination (direct contact) was considered important by Prendergast (2008).

In epidemiological studies of slaughterhouses aspects of internal climate and air flow were not clearly targeted (Delhalle *et al.*, 2008). The conjunction of the common bacterial airborne transmission on short distances especially under indoor conditions, the surface-type of *Salmonella* contamination (only the carcass surface is contaminated) and the often highly twisted shape of the slaughterline, combined with a humid internal climate and a loose separation between the slaughter "*per se*" area and the evisceration area, is worth considering.

As far as modelling the process of *Salmonella* surface contamination is concerned, further data are also needed about the mechanism of attachment/removal to/from the surfaces.

At scalding stage the assumption was made that *Salmonella* behaves closely to *E. coli* regarding the temperature of the water and that D-Value for chicken skin are close to that of pig, since no data could be found in literature.

At dehairing **s**tage, as the amount of faeces extruded by the pig was not documented in the literature available, expert opinion was used. During singeing, the gap concerned the time spent by the carcass, within the machine. In this case only one country provided the required data, and that figure was used. At polishing, there was a gap on the rate of *Salmonella* transfer from the pig to the machine. The assumption was made that faecal material behaves like loosely attached *Salmonella* in the scalding bath.

At evisceration, a most critical step due to the risk of gut perforation, there was a gap in the knowledge on bacterial transfer especially from the pig to the knife. The results obtained in an experiment on cross-contamination from steel surfaces to sponges and roasted chickens were used in substitution. The same data was used due to similar gaps at halving stage.

The bacterial load on carcasses changes considerably along the different steps in the slaughterhouse; e.g., scalding reduces the load, then it increases at dehairing, it reduces again at singeing and increases again at polishing. This explains, at least partly, also the large variability between abattoirs.

5.3.4. The cutting plant stage

Following the abattoir, the half carcass is cut into retail cuts which are in turn used for pig meat cuts, minced meat and fermented sausage. As regard *Salmonella* contamination and concentration all over the carcass, there seems to be shortage of data. The assumption of an even distribution may be strong.

Non-pig sources e.g. humans were not included in the model at this stage.

5.3.5. Preparation and consumption of pig meat

From factory to store, the maximum temperature required in the EU MSs is 4-8°C but the information about compliance with this requirement in the retail stage of the EU food chain is sparse.

Data on duration and temperature for transport from factory to retail shops were missing for numerous MSs including those modelled. Only the representative of two clusters could make them available.

Temperatures at retail level were only provided by few MSs of one cluster. The other clusters were modelled with the data of that cluster. As for storage time of pig meat in the refrigerator, only MSs from two clusters provided data.

Data on time and temperature on transport from retail to home and on household storage were missing and were important for the conclusions of the report.

Non-pig sources e.g. humans or other food ingredients were not included in the model at this stage.

5.3.6. Dose-response (hazard characterisation) and human resistance to illness issues

The ingestion of foodborne pathogens such as *Salmonella* does not inevitably result in infection and the latter into illness. Pathogenesis associated with *Salmonella* requires colonization and growth in the host gastrointestinal tract. Asymptomatic carriers are found and therefore colonization alone is not sufficient to cause disease. The host has a number of defence mechanisms, to remove or inactivate any pathogens before they can grow beyond a critical stage inducing a perceivable impact on health (Duncan and Edberg, 1995; Teunis *et al.*, 1999).

Dose-response assessment is considered a key ingredient of quantitative risk assessment, as it is presumed to provide the link between exposure to a pathogen and the probability of ensuing health effects (Teunis and Havelaar, 2000). Experimental studies tried to estimate the thresholds leading to infection or illness. However such studies are uncommon with humans as target species for understandable ethical reasons. Alternatively, the use of animals raises problems of uncertainty when extrapolating the results to humans.

Recently the concept of "single hit" was put forward (Teunis and Havelaar, 2000) and tends now to supersede the (minimal) infectious dose concept. It says that any single pathogen may be capable of causing infection in an individual.

The most frequently cited experiment in humans was performed in the USA by McCullogh and Eisele (1951). They worked with healthy volunteers who were fed and sometimes re-fed *Salmonella* contaminated food. Different *Salmonella* serovars were used. Immunity after experimental human infections due to *S.* Meleagridis and *S.* Anatum was studied by challenging the subjects at various intervals and dose levels. Some increased resistance was found in all twenty-three subjects studied although the degree varied considerably. On the first re-feeding using somewhat larger doses of the same strains, 16 of the 23 subjects did not become ill. Of 17 subjects being fed a second time using larger doses, seven again did not become ill. The authors mentioned that the great majority of illnesses produced by first or second re-feeding were milder than the initial illnesses. An increased resistance was present in some instances as long as nine months after the initial feeding. The above-cited experiment raised criticisms (Blaser and Newman, 1982) mainly directed at the protocol (e.g. the selection of young healthy men and the very large doses used), but the aspects of "resistance" were not strongly disputed.

Data from outbreak studies are also used trying to estimate the dose-illness relationship (Bollaerts *et al.*, 2008; FAO/WHO, 2002; Jones *et al.*, 2004). They refer undoubtedly to real life situations combining different food matrices, a wide range of doses and of human susceptibilities. The epidemiological calculations could give the opportunity to test the effect of host susceptibility factors such us age, suppressed immune function, use of certain medications. The WHO (2006) identified the children, the elderly, and pregnant and immuno-compromised individuals as particularly susceptible to foodborne disease. These groups are growing, for example UNFPA (2010) notes that in developed countries, one fifth of the population is 60 years or older; by 2050, that proportion is expected to rise to almost a third.

A study of *Salmonella* outbreaks found that 6% to 80% of the infected individuals develop symptoms (Chalker and Blaser, 1988) and in addition the clinical symptoms varied from mild transient diarrhoea to severe gastrointestinal illness. Therefore the expected response to contamination can vary to a large extent. This aspect of previous exposure to *Salmonella*, even when a clear illness for this reason occurred, is rarely available in the outbreak surveys. As a result of data gaps, when quantitative risk assessment of human salmonellosis is performed through modelling, assumptions are made about the probability of illness (Bemrah *et al.*, 2003; Rose *et al.*, 1995). Moreover, the accuracy of dose-response curves obtained in human feeding trials with only one *Salmonella* strain to reflect dose-response in naturally contaminated food was questioned (Oscar, 2004).

The use of outbreak data to estimate the dose response curve might overestimate (bias) the probability of becoming infected and thereafter developing illness given an exposure to *Salmonella*. This is because outbreak strains of *Salmonella* bacteria can be more virulent than those not involved in outbreaks.

In the case of human salmonellosis in the EU in relation to pig meat consumption, the consortium made the assumption of an equal host (human) susceptibility throughout the MSs. There may be doubts on this assumption. People from countries where the food gets more often contaminated might need a higher number of *Salmonella* bacteria to catch disease when compared to those less often exposed to contaminated food. The studies focused on travel-associated cases could to some extent help understand the question. The impact was found to be far from negligible (Hald *et al.*, 2004). Indeed, this could result from a different *Salmonella* pressure as well as the existence of different virulent dominating serovars in the countries. It can also be speculated that the absence or the very rare exposure *versus* repeated exposure to *Salmonella* (e.g. at low doses) through the food, combined to the composition of the diets consumed in the corresponding areas might interfere with the dose-illness response.

The choice of the dose-response model is always crucial for a QMRA. The WHO/FAO model has been used in this QMRA. The dose-response from WHO/FAO is assessed using data from outbreaks with mainly high exposure doses (17 to 10^{10} cfu) compared to the doses used in this QMRA (less than 11 cfu). In addition, the exposed individuals in the reported outbreaks don't capture the total range of population susceptibility. Using dose-response data from narrowly defined populations may not be representative in the total population, in particular the YOPI (young, old, pregnant, immuno-compromised) population.

5.3.7. Import and export, and trade within EU of pigs and pig meat

Data gaps occurred about imports of pig meat into the EU. Therefore external trade was not considered; the consequence can be expected to be low since the imports from outside the EU are small compared to the production within the EU.

On the other hand, the QMRA consortium also encountered difficulties when dealing with import/export trade within the EU. Due to the complexity of trade within the EU and the large data gaps the consortium decided not to include trade within the model. A refinement of the QMRA model would be to more explicitly account for the import/export and intra community trade of pig meat, pig meat products and live pigs. For MSs with a large external trade this could be important e.g. Denmark and the Netherlands.

The situation regarding *Salmonella* in such third countries is poorly documented. In case of a substantial increase of imports from third countries, this point should be considered.

5.3.8. Conclusion about the data gaps and assumptions

There are data gaps and critical assumptions of the model, and these should be considered when interpreting the results of the model. It is recommended to include methodologies to assess the quality of the data used as well as the quality of the assumptions and the communication thereof (Boone *et al.*, 2009).

6. Answers to the terms of reference (TOR)

The TOR will be answered in the following way: first the TOR (verbatim) posed in a box, then the answer from the QMRA consortium *(in italics)*, then balancing remarks and then the Panel's answer in a box.

6.1. Slaughter pigs

6.1.1. Relative contribution of *Salmonella* infections in slaughter pigs on cases in humans

Terms of reference 1

A quantitative estimation at Community level is requested of

> The relative contribution of *Salmonella* infections in slaughter pigs on *Salmonella* cases in humans. If an estimation of the influence of the prevalence of *Salmonella* in pigs at slaughter on human cases is not possible within the indicated time schedule, the influence on *Salmonella* prevalence in pig meat at retail should be estimated.

Quotation from the QMRA report:[15]

"The number of salmonellosis cases reported by each MS will not all be attributable to pork, nor will the three pork products considered here include all pork-related cases. The proportion of human Salmonella cases in the EU that are due to the consumption of contaminated pork/pig-meat products is unknown. As part of this project, a descriptive comparative analysis and interpretation has been carried out for the available Salmonella serovar data with particular emphasis on pigs and pork as well as an attribution model based on outbreak data. From the former analysis, a cautious assessment would be that around 10-20% of human infections in EU may be attributable to pigs and pork. However, this "guesstimate" is believed to vary considerably between MSs depending on, for instance, Salmonella prevalence in pigs and pork, consumption patterns and preferences, pig production systems and the relative importance of other sources, such as eggs and chicken. The "guesstimate" is to some extent supported by the outbreak data analysis. In order to obtain more reliable and quantitative estimates for the importance of different sources to human salmonellosis in the EU, it is recommended to develop a model for the attribution of human salmonellosis based on the microbial subtyping approach. This will require MS-specific data on the distribution of Salmonella subtypes in the most important sources and in humans. Particularly, the latter data have been very difficult to obtain, which is considered most unfortunate as these data are essential for understanding the trends and sources of human salmonellosis.

It should be emphasised that the Consortium originally intended to develop a hierarchical source attribution model based on microbial subtyping [16] *(Hald et al., 2004; Pires and Hald, 2010)using MS-specific animal and food data from the EU baseline surveys and human data as reported by the MS to the European Surveillance System (TESSy). It was, however, necessary to abandon this approach, since MS-specific data on the distribution of serovar and phage types in humans was not available. As an alternative, the Consortium made some descriptive comparisons of animal, food and human data, which were supplemented with results from a spatial analysis and an outbreak data analysis. All results were discussed in an attempt to make inferences and rank the most important sources of human salmonellosis in EU.* ***The result should, therefore, be considered as a guesstimate as it is based on very simple deductions:***

15 www.efsa.europa.eu/en/scdocs/scdoc/46e.htm

16 The principle of the subtyping method is to compare the distribution *Salmonella* subtypes in different sources (e.g., animals, food) with the distribution of subtypes in humans. The microbial subtyping approach is enabled by the identification of strong associations between some of the dominant subtypes and a specific reservoir or source, providing a heterogeneous distribution of subtypes among the sources. The approach utilizes a collection of temporally and spatially related isolates from various sources, and thus it is facilitated by integrated foodborne disease surveillance programs that is focused on the collection of isolates from the major food animal reservoirs of foodborne diseases (Pires *et al.*, 2009). This method typically focuses on sporadic cases and attributes infections to the reservoir level, meaning that the original infectious source is identified, whereas the route from reservoir (primary production) to consumer is not described.

The most important serovars in humans were S. Enteritidis (S.E.), S. Typhimurium (S. Tm.) and S. Infantis. Together these three serovars accounted for up to 81% of the human Salmonella cases in the period 2005 to 2008, with S. E. alone being responsible for between 54% and 64% of cases. When comparing between animals/food sources, table eggs (i.e. layer flocks) showed a higher proportion of S. E., which is in line with the results of the source attribution analyses based on outbreak data, where it was estimated that eggs were the most important source of human salmonellosis in EU countries, and that the majority of S. E. cases was attributed to egg consumption. Human S. Tm. infections represented between ca. 10-20% of all cases, and this proportion seems in fact to be increasing (relatively and absolutely)

Based on the comparison of phage types occurring in humans and animals sources, it is assessed that the majority of human S. Tm. cases are caused by pig-related phage types leading to the conclusion that the majority of human S. Tm infections overall is coming from the pig reservoir (see discussion p. 417 in the Consortium's report). Certainly broilers and beef also contribute to these infections, but as deducted in the report, the attributable proportion of these sources are assessed in general to be low due to low prevalences and/or lower impact through the food production chain. The latter is derived from the fact that some of the dominant S. Tm. phage types in broilers only occur in low frequencies in humans. Still, as illustrated by the spatial analysis there are geographical variations, where S. Tm. appears to be more prevalent in pigs in Western Europe and in broilers in Eastern Europe suggesting that broilers contribute relatively more in the latter region.

S. Enteritidis is recognized to be associated primarily with the poultry reservoir and particular laying hens and table eggs. Still, in Eastern Europe a small proportion of these infections may also come from the pig reservoir, as the prevalence of S.E. in pigs in this region generally is higher. This is also supported by the spatial analysis indicating a common cluster for S.E. in pigs and laying hens in the eastern part of Europe, which may add a few percentages to the overall pig-associated burden.

S. Derby is another very important serovar in pigs and most human infections of this type is assessed to originate from the pig reservoir. Although, it is also occurring in turkeys, the much lower consumption and production of turkey meat points at pork. In addition, it can be seen that some of the turkey-specific serovars (e.g. Saintpaul, Bredeney and Kottbus) have hardly any impact in humans. Of course this may be due to, for instance, lower infectivity of these serovars as compared to S. Tm., but without the detailed human data, it was not possible to estimate these differences.

Finally, the interpretation of the sources of human S. Infantis infections tended to be more complex, given its widespread occurrence including in animal feed. However, a certain proportion of S. Infantis infections and minor proportions of other serovars will most likely also be associated with pigs.

In conclusion, 10-20% of human infections in EU are guessed to be attributed to the pig reservoir. This is to some extent supported by the outbreak data analysis that indicated that meat products, particularly pork and beef, were important sources of S. Tm infections. This is furthermore in concordance with a recent attribution study done by Pires et al. (Pires, 2009; Pires et al., 2008), where the proportion of pork-associated cases acquired domestically was estimated for four EU countries: Denmark (3.6-9.7%), The Netherlands (7.6-15.2%), Sweden (0.1-0.3%) and UK (3.4%-3.7%)."

Remarks

The Panel has no reason to disagree with this statement but recommends caution using this estimate. In order to obtain more reliable estimates for the importance of different sources to human salmonellosis in the EU, it is required that available data is shared and communicated.

The concept of the *Salmonella* attributable to the pig reservoir is wider than the concept of looking at *Salmonella* attributable to pig meat. Conversely, there are *Salmonella* acquired from pig meat that may not be related to pig reservoir but to other reservoirs (human and animal reservoirs, also other food ingredients mixed with pig meat products).

For each MS the actual fraction of human salmonellosis cases is correlated with the *Salmonella* prevalence in pigs, import/export of live pigs and pig meat and the contamination levels thereof, national consumption habits and structure of pig and pig meat production.

The reported numbers could also vary due to the national reporting systems for human salmonellosis (Pires, 2009).

Pig meat and pig meat products are increasingly recognized as an important source of human salmonellosis. For instance in Germany five large outbreaks related to pig meat were reported from 2001 to 2005 (Jansen *et al.*, 2007). The consumption of contaminated pig meat or processed products was found to be associated with 20% of human salmonellosis in Germany, whereas *S.* Typhimurium, especially DT 104, was the most frequently isolated *Salmonella* serotype from pig meat in 1999 (Steinbach and Kroell, 1999). Also in the Netherlands, on average 23% of all salmonellosis cases for the period 2001 to 2008 were estimated to be associated with the consumption of pig meat (van Pelt *et al.*, 2009).

Since 2008, Denmark has experienced a huge outbreak of *Salmonella* Typhimurium U292 (Ethelberg *et al.*, 2008). The source of the outbreak has so far not been found and the outbreak appears to be ongoing. This outbreak has led to an extensive investigation using different methods among which are patient interviews (including focus group interviews and home visits), two case-control investigations, comparative analyses of patients' shopping lists obtained from supermarket computers, geographical and trace-back analyses, subtyping of isolates obtained in the surveillance programmes of food, animals and slaughterhouses in Denmark, microbiological analyses of food collected from patients' homes and of selected food production facilities. The results of these investigations indicated that the outbreak may be caused by several types of food vehicles. The main working hypothesis has been that the outbreak originates from pigs, but other ideas are also under investigation

BIOHAZ Panel's answer to the terms of reference 1

- The fraction of human salmonellosis cases attributable to *Salmonella* in pigs and pig meat will vary considerably between MSs and will mainly depend on i) the *Salmonella* occurrence (prevalence and numbers) in pigs and pig meat, ii) consumption patterns and preferences and iii) the relative importance of other *Salmonella* sources. Differences in the quality and sensitivity of the human reporting systems and testing methods between MSs make direct comparison of surveillance results between MSs difficult.

- From the descriptive and comparable analysis of the serovar distribution in animal sources and humans, a cautious assessment would be that around 10-20% of human *Salmonella* infections in EU may be attributable to the pig reservoir as a whole. However, the use of this estimate necessitates caution due to the lack of MS-specific data on the distribution of serovars in humans.

6.1.2. The effect of reduction of *Salmonella* prevalence in pigs on human *Salmonella* risk

Terms of reference 2

A quantitative estimation at Community level is requested of

The expected reduction of *Salmonella* cases in humans (or pig meat at retail) by a reduction (e.g. 5- or 10-fold[17]) of *Salmonella* prevalence in slaughter pigs (based on bacteriology in lymph nodes or serology at slaughter).

17 Interpreted as 80% or 90% reduction

Quotation from the QMRA report:[18]

"Marked reductions in cases can be achieved by reducing slaughter pig prevalence, and indeed for the MS2 and MS4 there is a strong linear relationship between slaughter pig lymph-node prevalence and the number of human cases (Figure 5). The major effect of reducing slaughter pig prevalence was to reduce the number of infected pigs with high infection/contamination loads entering the slaughterhouse, hence eventually reducing the number of highly-contaminated servings consumed by consumers.

For the MS2 and MS4, the linear relationship shows that factors that would be expected to introduce a non-linear relationship into the model, such as cross-contamination at the slaughterhouse, growth during retail storage and dose-response, although accounted for in the model, seem to have limited importance for the assessed relationship between pig prevalence[19] *and human incidence. Indeed, data from the EFSA baseline survey support a modest linear relationship) at a MS level, at least for infection and carcass contamination at evisceration. However, the results indicate that for low prevalence countries (MS1 and MS3) a 5-10% decrease in slaughter pig prevalence may result in a larger percentage reduction in human cases."*

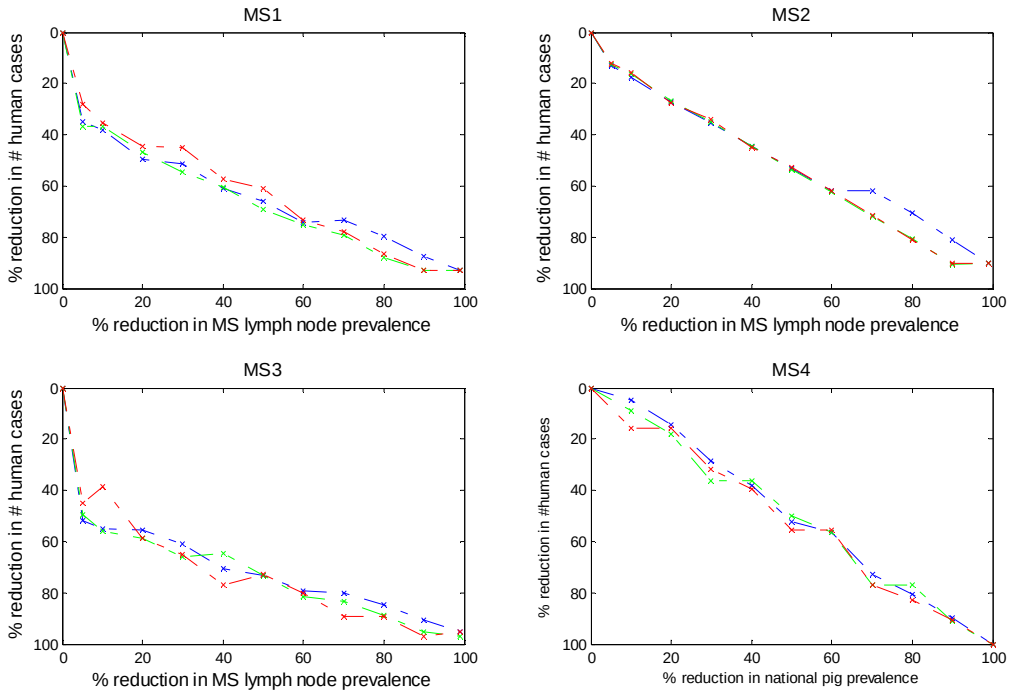


Figure 1: *Effect of reducing slaughter pig lymph node prevalence from 5 to 99% of the baseline national pig prevalence estimated within the baseline model, for each product type and for each case study MS (pig meat cuts – blue, minced meat – green and fermented sausage – red). y axes are inverted for clarity. Reductions in national pig prevalence are achieved by reducing the number of infected pigs within each batch according to a binomial trial, where the probability of "success" (i.e. subtracting a positive pig), p = {0.05, 0.99}. Hence, the number of infected pigs subtracted from an individual batch varies, but across all batches sent to slaughter the average reduction will converge to p. Small variations in the downward trend can be seen, for MS1 and MS3 in particular; these are due*

18 www.efsa.europa.eu/en/scdocs/scdoc/46e.htm
19 This is based on lymph node prevalence

to sampling error within the Monte-Carlo simulations. The starting lymph node prevalences for each cluster (MS exemplified) were based on the EU baseline studies[20].

Remarks

In the model a linear relationship between human cases and the slaughter pig lymph node prevalence would follow only if non-linear aspects of the model have a minimal impact. Those non-linear aspects are e.g. cross-contamination at the slaughterhouse, growth during retail storage, and dose-response. In this QMRA there is a very steep decrease in risk at low reductions of prevalence in MS1 and MS3 hence a positive feedback mechanism could be foreseen. For MS2 and MS4 the relationship between *Salmonella* prevalence and human health risk is broadly speaking linear.

If the relationship between *Salmonella* prevalence in pigs and risk of human salmonellosis are as outlined in Figure 2 then an 80% and 90% reduction in slaughter pig prevalence could result in an 80% and 90% reduction, respectively, of the number of human cases of salmonellosis attributable to pig meat. For low prevalence MSs such as MS1 and MS3 moreover, a reduction of 50% lymph node prevalence appears to result in an up to 80% reduction in human risk.

Hence, for MSs with low *Salmonella* prevalence (based on lymph nodes), a small reduction in *Salmonella* prevalence in pigs may result in a more than equivalent reduction in human salmonellosis cases possibly due to threshold effects on cross-contamination.

BIOHAZ Panel's answer to the terms of reference 2

It appears that an 80% or 90% reduction of lymph node prevalence should result in a comparable reduction in the number of human cases attributable to pig meat products.

6.1.3. Sources of infection for fattening pigs at farm level

Terms of reference 3

A quantitative estimation at Community level is requested of

The sources of infection for fattening pigs at farm level.

Quotation from the QMRA report:[21]

"We have investigated the relative importance of source of infection by simply turning off each source of infection within each MS model. The results are shown in Figure 3. The effect is striking – for MSs with a higher breeding herd prevalence (MS2, MS4) switching breeding herd prevalence to zero, hence assuming that the breeding herd cannot be re-infected from the finishing herd, removes the vast majority of infections at depopulation of the fattening herds. Conversely, removing feed or external contamination from the model does little to change the national fattening pig prevalence in the MS2 and MS4. The reverse trend is true in MSs with low breeding herd prevalence (MS1, MS3) as feed contamination seems to be the most important factor for the national fattening pig prevalence in these MSs. The results from the model suggest that breeding herd prevalence is a strong indicator of national fattening pig prevalence – i.e. if a relatively low number of breeding herds are positive, national fattening pig prevalence will be relatively lower than in MSs with more infected breeding herds. Finally, results from the model also indicate that external sources of contamination appear to have a general low impact on the fattening pig prevalence."

20 Please note that the reduction of human cases in the Y axis refers to reduction in cases attributed to consumption of contaminated pig meat

21 www.efsa.europa.eu/en/scdocs/scdoc/46e.htm

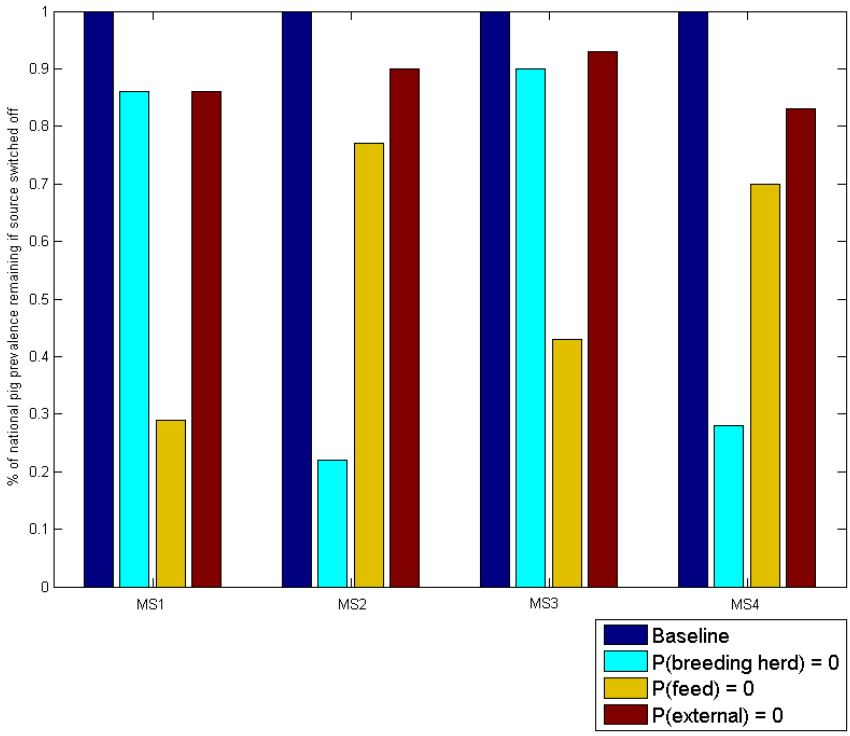


Figure 2: *Relative impact on predicted Salmonella prevalence of slaughter pigs for each MS if each source of infection is turned off. Baseline (dark blue), breeding herds all negative (light blue), feed all negative (light brown), no external contamination events (dark brown).*

Remarks

Theoretically, according to the QMRA following scenarios appear possible:

- By ensuring that breeder pigs are *Salmonella*-free a reduction of 70-80% in high prevalence MSs and 10-20% in low prevalence MSs can be foreseen;
- By feeding only *Salmonella*-free feedstuffs reduction of 10-20% in high prevalence MSs and 60-70% in low prevalence MS can be foreseen;
- By preventing infection from external sources of *Salmonella* (i.e. rodents and birds) a reduction of 10-20% in slaughter pig lymph node prevalence can be foreseen in both high and low prevalence countries;

Feed is an important source of *Salmonella*, its relative importance being high especially in low prevalence countries. A recent study (Wierup and Haeggblom, 2010) found that out of the 38 serovars which were isolated from vegetable feed ingredients (28) and from feed mills (10), 30 had also been isolated from human cases of salmonellosis diagnosed in Sweden 1997-2008. In addition, four (10.5%) of the serovars isolated from feed were identical to the serovars found among the 10 most common serovars of human cases of salmonellosis in the EU (EFSA, 2009b). These data support the previous EFSA statement that all serovars of *Salmonella* are considered as potentially pathogenic to human.

EFSA addressed the problem of microbiological risk assessment in feeding stuffs and the expert opinion which was issued, included contamination by *Salmonella* (EFSA, 2008c). It appeared that heat treatment is generally recognized as the most effective decontamination. Heat treatment effectively

reduces *Salmonella* concentration in feed. If recontamination occurs, *Salmonella* will grow in heat-treated feeds but much less in acid-treated feeds.

There are other external sources of *Salmonella* introduction (other than birds and rodents, e.g. water, staff, and wildlife) that have to be considered.

Salmonella can be introduced sporadically and in low doses into the herds, hence are hardly detectable. However, the risk of introducing *Salmonella* and subsequent spread can be reduced. Internal control of *Salmonella* essentially relates to hygiene and husbandry, both depending on housing which allows or not the appropriate implementation of the related practices on a daily basis. There have been numerous specific studies about the internal control of *Salmonella* as well as scientific reviews and reports (EFSA, 2006; Funk and Gebreyes, 2004; Ojha and Kostrzynska, 2007).

Residual infection from a previous batch is possible if appropriate hygienic measures (cleaning and disinfection between batches, all-in/all-out) are not applied. This is especially important in breeder herds where the sows are usually kept for up to several years and a more continuous production cycle is applied.

For outdoor pig farming the environment, in particular through rodents and birds can act as vectors for *Salmonella.* The occurrence of *Salmonella* in pigs which came in contact wild animal populations is often the result of a spill over from pig (or other animal) production at an earlier stage.

Salmonella in other farm animals such as cattle and poultry may also be a source for *Salmonella* in pigs.

Salmonella may also be introduced by equipment e.g. machines for manure handling, as well as by human traffic.

BIOHAZ Panel's answer to the terms of reference 3

Theoretically, according to the QMRA following scenarios appear possible:

- By ensuring that breeder pigs are *Salmonella*-free a reduction of 70-80% in high prevalence MSs and 10-20% in low prevalence MSs can be foreseen;
- By feeding only *Salmonella*-free feedstuffs reduction of 10-20% in high prevalence MSs and 60-70% in low prevalence MSs can be foreseen;
- By preventing infection from external sources of *Salmonella* (i.e. rodents and birds) a reduction of 10-20% in slaughter pig lymph node prevalence can be foreseen in both high and low prevalence countries;

6.1.4. Reduction of prevalence in slaughter pigs by control measures at farm level (pre-harvest stage)

Terms of reference 4

A quantitative estimation at Community level is requested of

The reduction of the prevalence in slaughter pigs by the most important potential treatments or control measures at farm level.

Quotation from the QMRA report:[22]

"Evidence that specific farm and transport interventions consistently work is sparse. This is presumably due to the more complex environment in which these interventions will have to be applied (relative to the abattoir) and the difficulty in standardising experiments to trial interventions. Hence, while the evidence for consistent effects is sparse, some farm interventions may well be effective. This was the conclusion of Denagamage et al. (2007) for vaccination, but no quantitative effect could be shown.

This lack of evidence for a consistent and/or quantitative effect meant that specific farm interventions could not be modelled. Therefore, in order to provide some assessment of farm interventions, we have modelled the effect of the varying mechanisms applied to farm interventions (e.g. modifying the dose-response for vaccination, lowering the contamination of pens due to cleaning).

Modifying the pig dose-response relationship to Salmonella exposure, perhaps by changing feed type, adding organic acids to feed/water, or vaccination, could have a significant effect in reducing slaughter pig prevalence within a MS, which would subsequently reduce the number of human cases. However, a large increase in this dose-response relationship – broadly speaking increasing the resistance of ALL of a MS's pigs such that an extra half-log to a log dose is needed to cause the same previous probability of infection – would be needed to see a significant change in the MS slaughter pig prevalence. This type of effect has rarely been described in the literature and it is debatable whether such an effect could be achieved consistently at a national herd level. Cleaning and disinfection appeared to have no effect.

Reducing feed contamination appears to be an effective measure in reducing slaughter pig prevalence and human cases and for large scale producers would translate into a widespread decrease in the exposure of pigs to Salmonella from feed. The effect was greater in MSs with a low prevalence (MS1) of positive breeding herds than in MSs with relatively high breeding herd prevalence (MS4).

The results of the farm intervention analysis suggest that farm interventions could achieve a significant decrease in fattening pig prevalence (and hence ultimately a reduction in human cases). The choice(s) of intervention will among other things depend on the farm production type and the breeder (supplier) herd prevalence. However, the significant reductions that would be required to achieve the same effect as slaughterhouse interventions would probably be unlikely for any single farm intervention."

22 www.efsa.europa.eu/en/scdocs/scdoc/46e.htm

Remarks

Due to the fact that infected pigs are the major source of *Salmonella* (chapter 6.1.3) and considering that the shedding of *Salmonella*, after infection and stress, usually is transient and that contamination can take place during transport, a **quarantine** phase (isolation and acclimatisation) for incoming pigs would be a suitable measure to reduce the prevalence of *Salmonella* in slaughter pigs. The quarantine accommodation, which requires a thorough cleaning and proper disinfection in-between batches of pigs, allows a slowdown of pathogen excretion after the first phase, which is critical just following arrival.

This quarantine period is necessary and recommended when new replacement breeding stock (gilts and boars) are introduced. When animals (gilts and boars) are tested *Salmonella*-positive, culling of these animals can be considered during this quarantine period. The situation is very different for farms receiving large numbers of pigs for growing or finishing purposes. While verified freedom from *Salmonella* could be difficult to achieve for piglet producers, it should be a more realistic proposition to achieve a very low risk status for *Salmonella*.

In slaughter pig herds safe sourcing is therefore the method of choice to prevent introducing *Salmonella*-infected pigs; i.e. pigs are introduced only from holdings or herds found free from *Salmonella*. In addition, age- (and where possible source-) segregated rearing can reduce *Salmonella* pressure and thereby avoid contamination spread throughout the entire farm, provided efficient biosecurity measures and all-in/all-out management is strictly applied (see below). In close relation to pig movements stands the role of trucks or other vehicles used for pig transportation (Mannion *et al.*, 2008). Only clean, disinfected and dry vehicles should be allowed to enter the farms to load pigs, hence avoiding contamination. Procedures to clean and disinfect trucks were outlined recently (Dee *et al.*, 2006). The drivers should wear clean boots and clothing when coming to contact with the pigs.

Only some points are mentioned here such **as age-segregated rearing, all-in/all-out management and related hygienic measures.** The goal is to avoid mixing pigs either of different sources or of a different age. Piglets of the same age group should constitute homogeneous groups (batches) and populate corresponding pens (compartments) without meeting other pigs. Mixing unacquainted pigs leads to considerable social stress. The latter induces an increased susceptibility to faecal shedding of *Salmonella*. The phenomenon was even found in young weaning pigs (Callaway *et al.*, 2006). When implementing all-in/all-out, the empty pen should be thoroughly cleaned. The pit below the slatted floor should be emptied as well. Then disinfection should take place according to the standard recommendations, followed by complete drying and a downtime period of a few days.

Contact between pigs of different health status, being either direct (mixing) or indirect with potential carriers of *Salmonella* (e.g. air flow, stockpersons). Airborne transmission on short distance has been clearly demonstrated (Proux *et al.*, 2001). People were also shown to transport *Salmonella* on their clothes or boots (Letellier *et al.*, 1999). The boots have to be washed before they are introduced into the disinfection footbath (Amass *et al.*, 2001). Dedicated boots and clothing per farm sector (compartment) are advised.

Hygiene routines - Residual *Salmonella* contamination was found on the floor and/or on pen partitions in more than 30% of the rooms before the loading of “new” pigs in fattening facilities (Beloeil *et al.*, 2004). This aspect of efficient cleaning and disinfection surfaced again recently in relation to *Salmonella* (Kuhnel and Blaha, 2005; Mannion *et al.*, 2007). Implementation of adequate procedures for cleaning and disinfection is imprtant. The procedures should include pen equipment such as troughs and other devices (Hotes and Krieter, 2009).

The sow herd is recognized as a reservoir of pathogens. *Salmonella* bacteria were shed by farrowing and lactating sows investigated in a follow-up study (Beloeil *et al.*, 2003). Piglets can get contaminated during suckling phase but events occurring at weaning (progressive loss of passive immunity, abrupt change of feeding regime, mixing of piglets from different litters greatly contributes to the spread of *Salmonella* infection (Nollet *et al.*, 2004).

The existence of clusters of pigs infected with *Salmonella* was described during the fattening phase due to litter, pen, and batch effects (Beloeil *et al.*, 2003). Hygienic measures aiming at maintaining a clean environment during the suckling and further phases are recommended. In this respect clear procedures were proposed with a hygienogram scoring system (Vangroenweghe *et al.*, 2009). The goal was to evaluate the relevance and the efficacy of the cleaning-disinfection protocols.

Housing, floor type - From surveys performed in countries where different flooring systems are used, it became apparent out that fully perforated floors ensuring cleaner pigs are more secure regarding *Salmonella* carriage by fattening pigs (Nollet *et al.*, 2004). A similar finding was recently reported (Hotes and Krieter, 2009). The oral-faecal route is generally accepted to be the predominant route of transmission for *Salmonella* among pigs. The risk of shedding *Salmonella* was increased in finishing pigs when the floor was solid with open-flush gutters, compared to partly-slatted floors (Davies *et al.*, 1997). Those aspects of flooring (solid *vs* slatted) could be source of conflicts even in official EU regulations when animal welfare and pig meat safety are both considered. Solid floors are supposed to provide a better welfare than slatted floor and are recommended in this respect (EFSA, 2005) but they might be more risky regarding food safety issues. On the other hand, straw-based systems when carefully managed do not increase the risk of *Salmonella* infection (BPEX, 2005). However when bedding is used, the risk of external contamination of the material has to be pointed out (e.g. through contact with wildlife like birds or rodents).

Feed and water at farm stage - Feed during storage, preparation, when home-made or when being delivered to the pigs needs to be protected against potential vectors of *Salmonella* (birds, rodents…). But the most documented issue is probably the physical structure of the feed (particle size) and the feeding methods (EFSA, 2008c) Meal feed was found to be less risky than pelleted feed (Wong *et al.*, 2004) and the difference was suggested to be a change in intestinal ecology (Davies *et al.*, 2004). The most plausible explanation seems to be that pelleted feed is transported more rapidly than meal feed through the gastro intestinal tract which minimizes the bacteria-reducing effect of the gastric acid (Mikkelsen et al, 2004). This is a problem since pelleted feed follows a heat treatment process which, if well applied, eliminates *Salmonella* contamination. Based on experiences from e.g. Denmark and Germany one third of the pelleted feed is therefore replaced by course ground meal in herds facing problem with *Salmonella* infections (Wierup, 2006).

Wet feeding is regularly reported to be less risky than dry feeding; knowing that the first option only concerns meal feed (Beloeil *et al.*, 2004; Farzan *et al.*, 2006). Liquid feeding systems develop a microflora that usually becomes dominated by lactic acid bacteria. Therefore the use of fermented liquid feed even when including by-products from the food industry show promising perspectives (Brooks, 2008). In their recent review on feeding management practices and feed characteristics associated with *Salmonella* prevalence, O'Connor *et al.* (2008) recommend caution when considering the effect of each practice taken separately.

It should be noted that wet feed whereas being protective against *Salmonella*, is a risk factor for growth of *Listeria* spp.

Chemical treatment of feed - Treatment of feed ingredients or compound feed with blends of organic acids or with formaldehyde products at suitable concentration, have been suggested (EFSA, 2008c). Chemical treatment has a residual protective effect in feed. **Acidification of feed** was put forward as a way to control *Salmonella* and a number of papers were published on the subject (EFSA, 2008c; Letellier *et al.*, 2000; Nollet *et al.*, 2004; van der Wolf *et al.*, 2001). Organic acids are known for their bacteriostatic activity. In Germany, two options were considered: Potassium diformate (1.2%) or free organic acids (0.9%: with 75% formic + 25% propionic) were tested in weaned piglets (Taube *et al.*, 2009). When compared to control diets, both options resulted in significantly lower counts of *Salmonella* in the stomach as well as in the distal part of the digestive tract. The authors recommend their use as diet additives against *Salmonella*. On the other hand, there is a fear of selection of acid tolerant clones of *Salmonella* that could enter the food chain (de Jonge *et al.*, 2003; Theron and Lues, 2007). It was also shown that some acid or formaldehyde treatments of feed may mask the presence of

Salmonella (Carrique-Mas *et al.*, 2007). However inclusion of organic acids in feed may assist in *Salmonella* control. Combinations of lactic and formic acids are often recommended (Creus *et al.*, 2007). Such feed treatments have been used for many years but it was stressed that whereas in infected herds they can reduce the *Salmonella* load, they will not eliminate the bacteria (Dahl, 2008).

The EFSA opinion on *Salmonella* control in feed (EFSA, 2008c) also highlighted the benefits of acid- or heat treatment of feed which has also recently been reviewed by Wales *et al.* (2010).

An additional solution to reduce the prevalence of *Salmonella* in the gut is, indeed, to manipulate the gut flora through the inclusion of specific compounds in the diet such as prebiotics, probiotics and antimicrobials.

Prebiotics are defined as "non-digestible" or "low-digestible" ingredients that benefit the host organism by selectively stimulating the growth or activity of one or a limited number of beneficial bacteria in the distal part of the digestive tract (Crittenden and Playne, 1996). Raw oats and unrefined wheat are examples of prebiotics. As a result, detrimental effects on the growth of unwanted bacteria like *Salmonella* could be expected. Unfortunately, to date, no convincing and reproducible results have been obtained in pigs in this respect and further investigations are needed as outlined by (Letellier *et al.*, 2000).

In recent years**, probiotic** bacteria have been considered as an alternative means of reducing pathogen loads in animal breeding and production units (Fedorka-Cray *et al.*, 1999; Genovese *et al.*, 2003).

The problem of increasing microbial resistance to **antimicrobials** and the resulting ban on their use as growth promoters in animal production has led to increased interest in alternatives to antimicrobials in animal production. Furthermore, antimicrobials should not be used in *Salmonella* control in pig production due to the increased risk of the emergence of antimicrobial resistant *Salmonella*, which is in line with published EFSA opinions (EFSA, 2006, 2008b, 2009c). In a survey conducted in Germany the application of antimicrobial treatments was also found to significantly increase the probability of *Salmonella* seropositivity (Hotes and Krieter, 2009). In mice the use of antimicrobials can have lasting deleterious effects on the capacity of the intestinal microflora to resist *Salmonella* infection (Croswell *et al.*, 2009). In pigs, the use of antimicrobials also disrupts the gut flora; it can oppose the growth of certain bacterial populations and thereby facilitate *Salmonella* proliferation (Wolf and Peperkamp, 2001).

As water can be a source of *Salmonella*, its potability needs to be monitored and any contamination avoided. Water tanks, pipes and drinkers should be cleaned, flushed and disinfected as part of a regular routine (SERAD, 2000).

Acidification of drinking water - the effect of adding organic acids to the drinking water on *Salmonella* shedding in finishing pigs two weeks prior to slaughter was investigated in four farms in Belgium (De Busser *et al.*, 2009). The acidified drinking water (pH = 3.6 – 4.0) decreased neither *Salmonella* shedding at the slaughterhouse, nor the level of carcass contamination.

Feed withdrawal for 24 hours prior to shipment to the slaughterhouse was found beneficial to reduce *Salmonella* in rectal contents at slaughter (Isaacson *et al.*, 1999). Results of another study indicated that feed withdrawal did not increase the prevalence of *Salmonella* colonisation or the risk of carcass contamination (Morrow *et al.*, 2002).

Rodents and pest control - *Salmonella* can often be transmitted through rodents, house flies but also birds. Continuous and effective rodent and insect control is an important component of *Salmonella* control (EFSA, 2006).

Concurrent diseases or infections and/or treatments - in field conditions the pigs are exposed to various challenges. The temperature of the environment can influence *Salmonella* shedding (Pires *et al.*, 2009). More generally speaking, the climatic environment the pigs are offered in our confined

farming systems clearly interferes with the severity of endemic diseases affecting either the respiratory or the digestive tract in infected herds. They often result in changes in the gut microflora through disruptions in feed intake and often temporary oral treatment. The follow-up surveys of grow-finishing pigs have shown that those infections and treatments enhance *Salmonella* faecal excretion in contaminated pigs. Hence, seroconversion against *Lawsonia intracellularis* and Porcine Reproductive and Respiratory Syndrome virus were found to significantly increase *Salmonella* shedding (Beloeil *et al.*, 2004).

Vaccination - vaccines are in limited use in some countries for *Salmonella* control in breeder pigs but may also be used in piglets. Their efficacy in reducing prevalence is not yet fully proven (Denagamage *et al.*, 2007). Efficient vaccination could be useful to control *Salmonella* on farm, but might interfere with the interpretation of serological test results in monitoring/surveillance programmes

On-farm lairage before shipment to slaughterhouse - for biosecurity and logistical reasons fattening pig units often have established a dedicated place where the pigs can be gathered in close vicinity to the loading bay before being transported to the slaughterhouse. Since pigs from different pens or buildings are mixed acute agonistic behaviours occur. Intense fighting inevitably takes place and the social stress incurred contributes to *Salmonella* shedding. Unfortunately this point has not yet been seriously investigated as on-farm lairage effect is usually merged with the transport effect. Lairage pens should be thoroughly cleaned and disinfected following each shipment.

The issue of mitigation options of *Salmonella* in pig production was also recently addressed by an EFSA opinion (2006) which conclusions remain valid. Some of the studies used an experimental approach sometimes in dedicated facilities whereas others were carried out in the field. The protocols were based on the knowledge of the main traits of *Salmonella* epidemiology, the goal being to test the relevance and/or the efficacy of actions taken at critical steps revealed by previous analytical surveys and known to be risk factors.

Due to the lack of good quantitative data for on-farm control measures (chapter 5.3.1) the model could only investigate hypothetical log-reductions. This investigation was done for a limited period of 500 days. To achieve a reduction of *Salmonella* infection in breeder pigs and subsequently in slaughter pigs and consequent reduction in human illness attributed to pig meat, a long term and full scale implementation of multiple control measures is required. The full effect of can probably be foreseen first after several years (5-10 years). Certain measures might have impact in the short term such as biosecurity, on-farm hygiene, changing feed type.

An outline of possible control measures can be found in Annex A to this report, and such measures were also evaluated in a previous EFSA opinion (2006).

Beside these sources there are several other sources of infection in slaughter pigs not being highlighted in the results of the QMRA. Among these are the internal and the external environment of the piggeries such as poorly managed herds, poor hygiene and wildlife.

BIOHAZ Panel's answer to the terms of reference 4

- To achieve control of *Salmonella* in slaughter pigs the two major sources should be controlled:
  - *Salmonella*-infected breeder pig herds and
  - *Salmonella*-contaminated feed
- The maximum impact of achieving control of these two sources is shown in the answer to the terms of reference 3.
- Eliminating those sources may not be practically achievable. Nevertheless, all efforts have to be directed at reducing the prevalence in breeder herds and the *Salmonella* contamination of feed, so as to minimize infection in slaughter pigs.
- Beside these sources there are several other sources of infections in slaughter pigs, namely internal and the external environment such as other farm animals on the premises and wildlife.
- Effective implementation of biosecurity measures (e.g. age- and source-segregated rearing including cleaning and disinfection procedures between batches) and Good Hygiene Practices (GHP)/Good manufacturing practices (GMP) are important for becoming and remaining a *Salmonella* low risk holding.
- In MSs with high prevalence in breeder and slaughter pigs, control of *Salmonella* in breeder pig herds can be the first step to control *Salmonella* in slaughter pigs.
- Measures to increase the pig's resistance towards *Salmonella* infections include change of feed type and/or vaccination.
- General *Salmonella* control measures should always be applied, but where the particular emphasis shall be placed will depend on the epidemiological situation of the herd.
- A hierarchy of control measures is suggested - a high prevalence in breeder pigs needs to be addressed first, followed by control of feed and then control of environmental contamination.

6.1.5. Impact of transport, lairage and slaughter process on contamination of carcasses

Terms of reference 5

A quantitative estimation at Community level is requested of

The impact of transport, lairage and slaughter process on contamination of carcasses.

Quotation from the QMRA report:[23]

"Due to the unavailability of data on the contamination of skin, it was not possible to model the cross-contamination of skin during transport and lairage. Therefore the contamination on the skin was estimated at the point of slaughter (scalding) (using data from Davies et al., 1999) and used as input to the Slaughter & Processing module.

Within the Slaughter & Processing module, cross-contamination has been extensively modelled. The QMRA results predict that, for all four MSs, the evisceration step in a large slaughterhouse model greatly increases both the microbial load and also the prevalence of carcass contamination. This increase is due to the possibility of the gut being punctured during evisceration, therefore allowing the carcass (and subsequent carcasses on the line) to become highly contaminated. The increase in prevalence is also attributable to house flora[24]*, although the microbial load transferred from this source to the carcass is assessed to be low. In addition, the load and prevalence is increased during the dehairing phase (primarily due to faecal leakage) in MS2 and MS4, which had the higher infection prevalence at the point of slaughter. In the small slaughterhouses, the microbial load decreased at scalding and belly opening but there was a small increase in the prevalence of contamination during the combined step of trimming/singeing."*

Remarks

Transport and lairage did not have a major impact in the model on human cases given the data used. However, this does not preclude an impact if the transport and lairage conditions are outside the data ranges used in the model. The role of transport and lairage on contamination of skin is not quantified in the model.

Rostagno *et al.* (2003) concluded that abattoir holding pens have to be considered as a significant hazard for *Salmonella* contamination, serving as infection source. This corroborates results published before (Hurd *et al.*, 2001b).

Schmidt *et al.* (2004) described that cleaning/disinfection effectively reduces the amount of *Salmonella* and hence cross-contamination of pigs during their stay in the lairage. On the other hand, of course, those bacteria already harboured by the pigs when they arrive in the lairage, will remain, and this is not affected by the lairage cleaning procedure.

The three subsequent steps of: transport of pigs from the farm gate, lairage phase and slaughtering itself up to (and including) chilling the carcass, cover altogether the phase of the pig meat chain known as "harvest". The term was defined in this way in a recent EFSA opinion (2006). The continuous flow of contaminated pigs at the slaughterhouse has been for many years, highly suspected to induce risks for contamination of the carcasses at the end of the slaughter process (Berends *et al.*, 1997). A recent longitudinal study carried out in the USA pointed out the role of poorly cleaned and disinfected trucks and holding pens (lairage) in *Salmonella* spread throughout the chain (Dorr *et al.*, 2009). *Salmonella* contamination of the carcass remains at the surface, the bacteria is not detected in the muscle (Scherer *et al.*, 2008). Therefore, at the slaughter stage the major effort relates to hygiene rather than to infection "*per se*". However, estimating the contribution of each step of the chain (i.e. from transport to the end of the slaughter process) to carcass contamination remains a major challenge. The conditions encountered are highly variable in a given step of harvest operations, depending on the equipment in place and the hygiene routines being implemented. Additionally the events are naturally organised in a sequence and accordingly the efforts displayed at *Salmonella* prevention at an early stage can be reduced to nothing as soon as poor attention is paid to *Salmonella* exposure in the later stages. On the other hand, neglecting the pre-harvest stage inevitably leads to maintaining the flow of *Salmonella* into the slaughterhouse.

23 www.efsa.europa.eu/en/scdocs/scdoc/46e.htm

24 House flora is defined as the *Salmonella* contamination of the equipment, machines or other objects in the slaughterhouse that is never completely removed. It therefore acts as a permanent source of potential contamination of carcasses.

An impact of transportation stress on the shedding rate has been observed (Hurd *et al.*, 2002; Marg *et al.*, 2001) as well as a rapid infection of pigs during lairage (Hurd *et al.*, 2001b; Rostagno *et al.*, 2003). Pigs harbouring *Salmonella* in their gut can revert to excreting the bacteria in their faeces (Williams and Newell, 1970). The effect of separate transport, lairage and slaughter depending on the farm status (logistic slaughtering) was assessed and suggested (Boes *et al.*, 2001; Swanenburg *et al.*, 2001b). Trucks used for transport can remain contaminated even after being cleaned and, thereby, be a source of *Salmonella* for incoming pigs (Dorr *et al.*, 2009; Mannion *et al.*, 2008). The skin of the pigs can easily get contaminated on board since physical contact with the floor is favoured through the fighting behaviour the pigs use to express and through the truck movements as well. When multiple sites are sampled on pigs at the slaughterhouse, the rectal content and the tonsils usually show the highest prevalence whereas the carcass, at the end of the process does the lowest (Swanenburg *et al.*, 2001b). The slaughter process itself might help *Salmonella* excretion in contaminated pigs. For example when pigs are placed in CO_2 gas mixture faeces are often expelled. The recumbent posture rapidly adopted by the pigs combined with a non perforated floor in the CO_2 stunning chamber often lead to skin fouling. Since carcass contamination by *Salmonella* exclusively relates to surface contamination those aspects of cleanliness are of utmost importance along the chain. However, few investigations were specifically targeted on skin or carcass contamination with *Salmonella* throughout the three steps of the harvest phase, looking for critical points in this respect.

A study in a small slaughterhouse in Ireland measured the number of *Salmonella* on three carcass surface locations as target. The sampling was performed at different stages along the process (Bolton *et al.*, 2002). Whereas the prevalence of *Salmonella* spp. on pigs at the farm was 27%, it decreased to 10% after pre-slaughter washing. Then stunning and bleeding showed a clear increase in *Salmonella* contamination (50%). Hair removal (i.e. scalding, dehairing and singeing) resulted in a significant decrease in viable bacterial counts. Reciprocally a significant increase was observed after pre-evisceration washing and finally chilling resulted in another increase. In a study conducted in three large abattoirs in the USA with high line speeds (around 1000 carcasses per hour), the carcasses were swabbed at three points in the processing chain. *Salmonella* prevalence was 4.4%, 1.1%, and 0.4% after singeing/polishing, after the final rinse, and after 24 h of chilling, respectively (Saidealbornoz *et al.*, 1995).

Through a meta-analysis study, other authors clearly place chilling as a major operation in order to reduce the prevalence of *Salmonella* on pig carcasses (Gonzales Barron *et al.*, 2009). Recently, a survey was carried out in the ten largest Belgian pig slaughterhouses (Delhalle *et al.*, 2008). The carcasses were sampled in the chilling room two to four hours after slaughter. Swabs were used and four different zones were investigated totalling 600 cm². Large differences were found among the slaughterhouses. The main factors which were found to reduce carcass prevalence of *Salmonella* were the use of steam for scalding (instead of a tank), a second flaming after polishing, and complete cleaning and disinfection of the splitting machine several times per day. A longitudinal study performed in France (Rossel, 2009) in five slaughterhouses involved 177 batches of pigs from 63 farms belonging to a *Salmonella* monitoring programme. Before the pigs were unloaded at the slaughterhouse, the floor of the lairage pens was swabbed. Just before stunning the pigs were skin swabbed at three locations and at the end of the slaughter process, before chilling, the carcasses were also swabbed. Blood samples for *Salmonella* antibody detection were taken at bleeding. Due to the specificities of the issue to be addressed, Bayesian statistics were used. The goal was to point out the marginal impact on carcass contamination of the main factors which were supposed to have an influence and that were recorded. The conditional probabilities were assessed. The results could not show any positive relationship between the *Salmonella* herd serological status, and both, skin contamination at stunning and carcass contamination.

On the other hand, carcass contamination was directly related to skin contamination of the live pigs at stunning. Hence the probability for *Salmonella* on the carcass dropped from 59% to 36% depending on the presence or absence of the micro-organism at stunning. In turn, skin contamination at stunning was found to be directly affected by floor contamination and the holding time in the lairage. As for the floors, the probability to detect *Salmonella* on the skin dropped from 71% to 36% depending on the

detection of the micro-organism or not. Long-lasting lairage duration (e.g., more than 10.3 hours) decreased the probability of *Salmonella* detection on the skin at stunning (from 87% to 56%). It was seen that those long residence times in the lairage were for the first batches of pigs being placed in pens after thorough cleaning following the workday (Rossel, 2009).

In the UK, a study was focused on the thermal stages of the slaughter process (Richards *et al.*, 2009). The results showed that pre-washing before scalding has the potential to improve carcass hygiene. The study also showed that some areas are not effectively heated at singeing. All the reported studies clearly show the complexity of the numerous events taking place from the farm gate to chilling. Some conflicting results can be found in literature but maintaining the pigs clean from the farm gate down to bleeding seems to be in favour of a lower probability of contaminated carcasses.

The scalding system as well as the strictness of hygiene implementation during the other steps of the slaughter process also interferes with carcass contamination. In many cases the latter strongly depends on the type of material used or on the design of the slaughter line and the overall organisation of the slaughter plant. Unfortunately most of those potential risk factors are of a difficult objective appraisal. Despite many reports about *Salmonella* at the harvest phase (Botteldoorn *et al.*, 2003; Swanenburg *et al.*, 2001a; Swanenburg *et al.*, 2001b) the risks of carcass contamination attributable to the different factors involved still need further investigation.

House flora is defined as the *Salmonella* contamination of the equipment, machines or other objects in the slaughterhouse that is never completely removed. It therefore acts as a permanent source of potential contamination of carcasses. The importance of house flora is that it may grow in biofilms and hence may be an independent reservoir.

BIOHAZ Panel's answer to the terms of reference 5

Unhygienic practices enabling direct and/or indirect faecal contamination during transport, lairage and, particularly, slaughter and dressing, increase the risk of carcass contamination with *Salmonella*. Due to insufficient quantitative data on the microbial load of *Salmonella* on the skin, it was not possible to quantify the effect of cross-contamination during transport and lairage. During slaughter and dressing, the evisceration step was found to be a critical procedure for cross-contaminations and thus for the *Salmonella* occurrence on carcasses.

6.1.6. Expected reduction of *Salmonella* cases in humans by control measures during transport, lairage and slaughter

Terms of reference 6

A quantitative estimation at Community level is requested of

The expected reduction of *Salmonella* cases in humans (or pig meat) by the most important potential control options during transport, at lairage or during the slaughter process.

Quotation from the QMRA report:[25]

"Transport and lairage interventions (logistic transport and slaughter, cleaning and disinfection), even assuming 100% implementation and achieving 100% effectiveness, of the intervention, were assessed to have an insignificant effect in reducing the probability of human illness.

25 www.efsa.europa.eu/en/scdocs/scdoc/46e.htm

The effects of reducing concentrations on carcasses pre-chill by some decontamination step are shown in Figure 3:

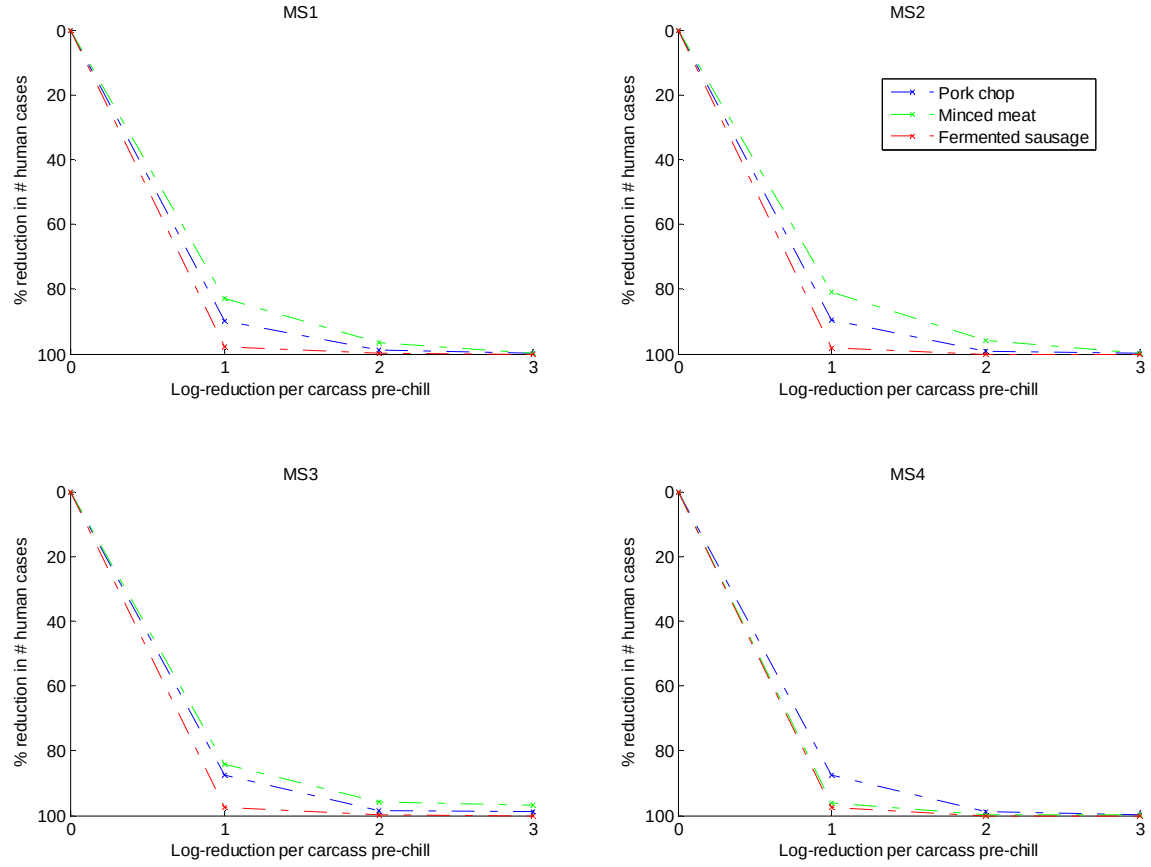


Figure 3: *Effect of reducing concentrations across all contaminated carcasses in each MS by one, two, and three logs immediately before chilling of the carcass (pig meat cuts – blue, minced meat – green and fermented sausage – red). For each MS, a reduction of two logs appears to be sufficient to reduce cases by over 90%*[26].

Marked reductions can be achieved by preventing faecal leakage or applying some decontamination measure at the slaughterhouse. An intervention that could consistently achieve a two log decontamination of carcasses pre-chill could reduce the number of cases by over 90% in all MSs. Further reductions can be achieved by further reducing concentrations on carcasses at pre-chill (e.g. a reduction of three logs) with all case study MSs predicted to achieve a very high reduction (95-100%) in their number of cases. Practical non-chemical interventions have been shown to produce reductions in the order of one to two logs (90-99%) (Christiansen et al., 2009). If such interventions are shown to be as effective when scaled up and applied across a MS's slaughterhouses, it is concluded that a control measure that reduces Salmonella concentration on carcasses pre-chill would be a viable option for reducing the number of human salmonellosis cases."

Remarks

26 Please note that the reduction of human cases in the Y axis refers to reduction in cases attributed to consumption of contaminated pig meat

Contamination of pig carcasses with *Salmonella* results from exposing the surface of the carcass to potential sources such as faecal material or contact with contaminated aerosols or equipment. Therefore, adherence to good manufacturing and good hygiene practices within the slaughter facility combined with a reduction of *Salmonella* load entering the slaughter plant through the live pigs, provide broad space for effective control measures aiming at lowering carcass contamination (Huffman, 2002). This point is hardly disputable. However it remains challenging since substantial efforts are required all along the process.

Technologies aiming at reducing the surface contamination of carcasses at the end of the slaughter line before chilling were tested (Dickson and Anderson, 1992). Carcass decontamination refers to a variety of methods. Potable water but also solutions of short chain organic acids were tested. Decontamination with hot water (around 80°C during 15 seconds) was found to be effective in reducing the number of pathogens including *Salmonella* on pig carcasses (Jensen and Christensen, 2002). The water used could largely be recycled, but some meat discoloration was observed. As for the use of organic acids, bacterial counts were reduced by 1-2 $\log_{10}$ cfu/area of tissue surface (Gill *et al.*, 1995; Siragusa, 1995). The antimicrobial effect of short chain acids (e.g. lactic, acetic, formic and propionic) is related to acid concentration. However, at high acid concentrations, detrimental effects were detected on product quality (colour, flavour). In addition, the temperature of the solution was found to play a role. Before spray treatment with organic acid (e.g. lactic acid), the carcass might be washed or submitted to hot steaming in a dedicated cabin. This can improve efficacy and reduce carcass discoloration. Lactic acid is often used at 2% concentration (Pipek *et al.*, 2006). Recently in Denmark four decontamination technologies were compared in relation to their cost-effectiveness: hot water, steam ultrasound, steam vacuum and lactic acid (Lawson *et al.*, 2009). Hot water consisted in carcass exposure to water (about 80°C) during 15 seconds; steam ultrasound directs 130°C steam through a whistle that generates a high frequency sound (around 30-40 Khz); the steam vacuum is applied before evisceration or after splitting: the vacuum removes faecal material and the steam deactivates bacteria; finally lactic acid was used at 2% after passing through a washing cabin. Among the assumptions being made for the analysis, it was supposed a full-scale implementation of the technologies in the country. From the study it was shown that these control measures were relatively cost-effective compared to the pre-harvest control measures such as on the feed, decontamination in order to reduce the *Salmonella*-related food risk in pig meat.

One type of measure is preventing faecal leakage and the other type is carcass decontamination. In the model, transport control measures were found to have an insignificant effect in reducing the probability of human illness. The choice of measures should be done on a case-by-case basis having regard to the pre-harvest prevalence of *Salmonella* and the capacity, design, technology, and hygiene practices of the slaughterhouse. An outline of possible control measures can be found in Annex A.

BIOHAZ Panel's answer to the terms of reference 6

For each MS, a reduction of two logs (99%) of *Salmonella* numbers on contaminated carcasses would result in more than 90% reduction of the number of human salmonellosis cases attributable to pig meat consumption. A reduction of one log (90%) would result in more than 80% reduction of human cases.

This could be achieved through measures preventing direct and/or indirect faecal contamination during transport, lairage and, particularly, slaughter and dressing processes; and/or by effective carcass decontamination.

6.2. Consideration of multiple interventions

Quotation from the QMRA report:[27]

"EFSA (2006) concluded that it was not possible to control Salmonella with the adoption of just one measure. In other words, the control of the Salmonella can only be achieved by the introduction of multiple interventions across the farm-to-consumption pathway.

In order to investigate the impact of multiple interventions we considered a number of combinations of interventions; three are highlighted to show general trends from this preliminary analysis:

1. *Change to wet feed and one log decontamination post-dehair*
2. *One log modification of dose-response with one log decontamination post-dehair*
3. *Change to wet feed and one log decontamination pre-chill*

The analysis was carried out for MS4 only and it is concluded that a combination of interventions can, if applied judiciously, produce reductions greater than the sum of the individual interventions alone. The major reason for this is that both interventions will affect the contamination level of carcasses. We also predict similar results for MS1, MS2 and MS3 although, of course, the impact of the combination of interventions that achieve the greatest reductions will be dependent on the situation within a particular MS, in particular the contamination levels of carcasses.

In summary, the farm and transport interventions are likely to vary in their ability to change slaughter pig prevalence by a sufficient amount to change numbers of salmonellosis cases. However, a combination of farm interventions applied across a large proportion of farms is likely to have a cumulative effect in reducing slaughter pig prevalence. Probably of extreme importance, but not investigated here, is the rate of uptake and correct application of interventions by farmers – if this is not universal across a MS the effect in reducing human illness will be reduced. The model results lead us to suggest that those MSs with a high breeding herd prevalence should focus on these herds in order to reduce the burden of infected new stock entering the weaning/growing/finishing stages. However, from the results of the intervention analysis we predict that it may be more effective for MSs with a low breeding herd prevalence to focus their attentions on feed and other sources of infection.

From the current evidence, it would appear that specific slaughterhouse interventions are currently best placed to produce consistently large reductions in the number of human cases. For high breeding prevalence MSs, reducing infection in breeders would seem to be an important control measure as has been successfully implemented by the poultry industry. However, the hypothetical reductions and multiple interventions investigated here suggest that MSs can achieve larger reductions by targeting farm and slaughterhouse together. Reducing the prevalence at farm level is also considered important for preventing the transmission of Salmonella from pigs to other livestock species such as laying hens and broilers, where the prevention and control efforts are focused on the farm.

This does therefore suggest that as a first step, if breeding herd prevalence is high it should be controlled as a first measure – feed and external contamination of finishing pigs can then have a positive effect once breeding herd infection is reduced to low levels (perhaps below 5-10%)."

27 www.efsa.europa.eu/en/scdocs/scdoc/46e.htm

Remarks

The pig meat food chains are not limited to an individual MS but include the whole of EU.

There is no combination of risk mitigating measures without decontamination presented in QMRA analysis. Some multiple control measures have a synergistic effect depending on the combinations you choose for each MS.

Measures aiming at producing safe pig meat through decontamination of the carcass should not be perceived and used as a substitute to hygiene practices at the earlier stages of the pig meat chain such as at pre-harvest. Public concerns relating to animal hygiene issues have been raised in particular in intensive livestock production (Burton, 2009). The proliferation of *Salmonella* in pig herds, even without clinical signs, is obviously exposing the environment to contamination through the aerial emissions of the bacteria from the piggeries. It also results in the risk of spread of the pathogen present in the waste (e.g. slurry) on the land, on grass and on diverse crops thereby contributing to expose of cattle and other animals through water and plant consumption (Baloda *et al.*, 2001). To some extent humans are also exposed, since it has been demonstrated that *Salmonella* not only can adhere to plants like vegetables after fertilization with contaminated slurry or manures, but that it can also colonize the plant "*per se*" through the roots (Cooley *et al.*, 2003; Klerks *et al.*, 2007). There are many transfer routes for *Salmonella* moving through the environment. The ubiquitous trait of the bacteria makes it able to survive in a variety of conditions and therefore any effort to reduce the *Salmonella* burden in the environment e.g. through efficient control measures all along the pig meat chain, should be encouraged.

The optimal choice of control measures might vary from country to country depending on the epidemiological and socio-economic situation.

BIOHAZ Panel's answer on multiple interventions in the food chain:

- Beyond compliance with EU legislation and GMP/GHP, it appears that control of *Salmonella* in pig meat as a public health problem should be based on the individual MSs situations and include combinations of following interventions: *Salmonella*-free (low risk) breeder pigs, *Salmonella*-free feed, cleaning-disinfection between batches both on-farm and during lairage, avoidance of faecal contamination during slaughter and decontamination of the carcasses. Efficient vaccination will also be useful to control *Salmonella* on farm, but might interfere with the interpretation of serological test results in monitoring/surveillance programmes. The QMRA results could give some guidance on appropriate combinations.

- From the current evidence, it would appear that specific slaughterhouse interventions are, at present, more likely to produce greater and more reliable reductions in human illness, at least in a shorter timeframe than can be achieved at the farm in high prevalence MSs. However, the hypothetical reductions and multiple interventions investigated with the current risk assessment model suggest that MSs can achieve more effective reductions in human cases by targeting both farm and slaughterhouse.

6.3. Breeder pigs

6.3.1. Relative contribution of *Salmonella* infections in breeder pigs on *Salmonella* prevalence in slaughter pigs

Terms of reference 7

A quantitative estimation at Community level is requested of

> The relative contribution of *Salmonella* infections in breeder pigs on *Salmonella* prevalence in slaughter pigs (based on bacteriology in lymph nodes or serology at slaughter).

Quotation from the QMRA report:[28]

"Sensitivity analysis of the model shows that the relative importance of parameters varies according to MS parameter estimation. The main example of this is the relative sensitivity of the model output (i.e. the variation in the within-batch prevalence of infection at slaughter age) to the burden of excretion by the sow if it is infected. In two MSs (MS2 and MS4) this is the foremost or second-most important parameter in describing the variability in the within-batch prevalence. It is no coincidence that these two MSs have relatively high breeder pig herd prevalence (44% and 13% respectively). For the other two MSs, with relatively low breeder pig herd prevalence, then the load shed by the sow is a relatively unimportant factor compared to the load being shed by the piglet, or that within the feed.

Further analysis of the model shows the reason for this dichotomy: if the sow is infected and shedding at high levels, then commonly (although not always) this will mean one or more piglets will become infected; when this occurs then the shedding of Salmonella by infected pigs, at the farrowing stage or later, dominates the risk. However, in MS1 and MS3 infection of the sow is relatively rare, and so the infections within the herd are generated by an initial infection of a piglet, weaner, etc via either feed or external contamination. The sensitivity analysis also identifies another trend: that once a slaughter pig is infected, the subsequent shedding of Salmonella more than outweighs the contribution of contamination within the environment provided by feed and/or the external environment. In summary – breeder pig herd prevalence is a strong predictor of national pig prevalence, and while only simply modelled, scenario and sensitivity analysis suggest that mixing infected pigs with uninfected pigs at any stage of production will be an important source of infection. Finally, feed becomes an important source of infection once contamination of the environment by sows or other slaughter pigs is reduced to low levels (p 151-2).

The difference between MS' slaughter pig prevalence is largely described (but not completely) by breeder pig herd prevalence (p 377 13.2.1)

Breeding herd prevalence has already been established as a significant factor within the model via sensitivity analysis – broadly speaking, low breeder pig herd prevalence (low number of positive piglets) equals low slaughter pig prevalence and vice versa.

The reason for this is that breeding herd prevalence has already been shown to dominate the risk of positive pigs at slaughter to a degree that the trend in the change of breeding herd prevalence will outweigh all other factors. The result of the breeding herd analysis is shown in Figure 4: This analysis looks at a broad range of plausible breeding herd prevalences (as taken from the EFSA breeding survey), but uses the farm management systems of MS4. The trend observed with this MS4 management model will be much the same as it will for the other three MSs. It is clear from Figure 5 that for MS4 breeder pig herd prevalence is predicted to be strongly correlated with slaughter pig prevalence, and hence is also strongly correlated with the risk of illness in humans. Given the strength

28 www.efsa.europa.eu/en/scdocs/scdoc/46e.htm

of association between breeder pig herd prevalence and slaughter pig prevalence within the model, this same trend will be seen for each case study MS."

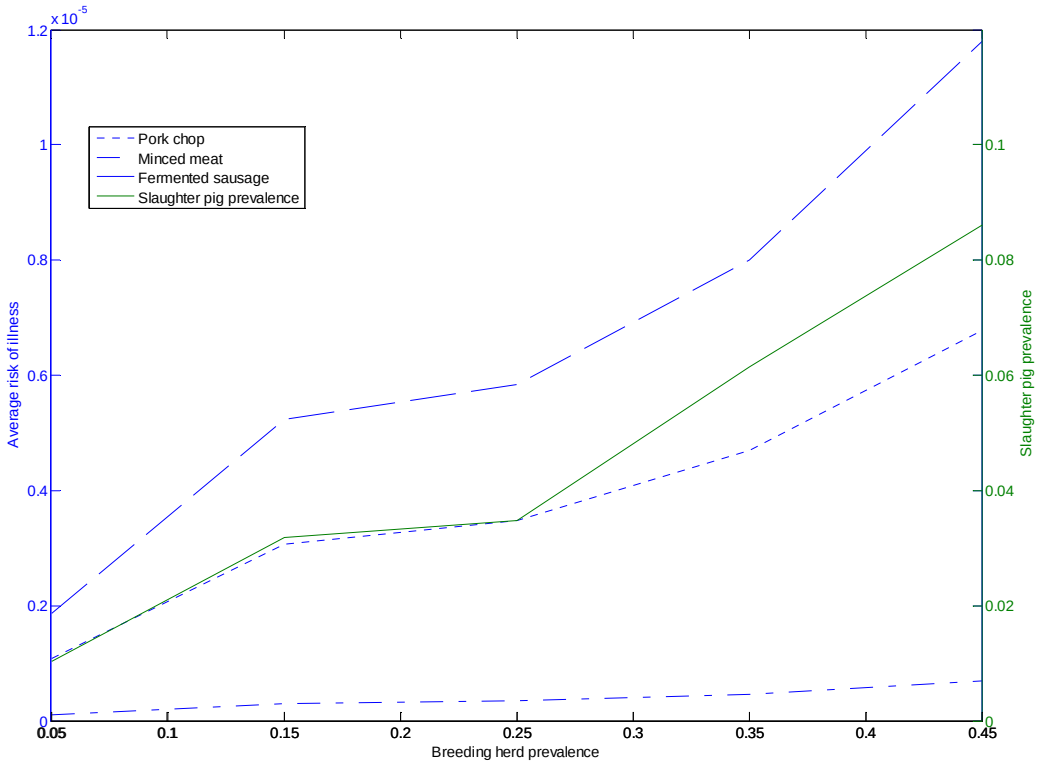


Figure 4: *The effect of breeding pig herd prevalence on the national slaughter pig prevalence (right-hand axes) and the average risk of illness per serving in humans (left-hand axes).*

Remarks

The correlation between *Salmonella*-positive sows and slaughter pigs has been examined in several studies (Beloeil *et al.*, 2003; Lurette *et al.*, 2008; Merialdi *et al.*, 2008), but many of them have concluded that breeder sows might not be a major or even important source of infection for finishing pigs (Davies *et al.*, Mejia *et al.*, 2006, 1998, Ngasaman *et al.*, 2008). Some evidence has nevertheless been presented for the sow to be a possible source of exposure to suckling piglets (Davies *et al.*, 1998; Funk *et al.*, 2001; Letellier *et al.*, 1999), but the pathways may be diverse.

Contradictory results have led to the conclusion that point estimates of *Salmonella* prevalence and serovars cannot be considered as reliable indicators of the prevalence of *Salmonella* on the farms (Beloeil *et al.*, 2003; Funk *et al.*, 2001). Differences in the result on the correlation between breeder and slaughter pigs may also be attributable to other factors such as sampling and processing of samples but the magnitude of this effect cannot be assessed at this point in time.

Although in some studies piglets were considered to acquire infection in the nursery premises rather than from their sows (Kasemsuwan *et al.*, 2008), other studies have demonstrated a correlation between the sow herd *Salmonella* status and that of the finishing pigs (Nollet *et al.*, 2005). According to Lurette *et al.* (2009), early infection, occurring between birth and weaning, seemed to be critical for *Salmonella* spread within the batch and possibly within the herd, at least when birth and growth took place in the same location. In the same research, the results indicated that maternal protection may lower the probability of *Salmonella* infection among piglets during the first month.

Since indirect transmission is probably the main route of spread, the probability of infection depends on the quantity of *Salmonella* in the pigs' environment (Lurette *et al.*, 2008). The type of housing and management measures for the breeder herds therefore influence the level of environmental exposure (Lurette *et al.*, 2009). However, it is logical to assume that when a sow is infected by *Salmonella* and sheds the agent in faeces, exposure and subsequent infection of the piglets cannot be avoided. The environmental exposure is also primarily the result of faecal shedding of *Salmonella* from infected pigs in the breeding unit and nursery premises. In the absence of detailed studies and optimal bio-security that eliminates this environmental contamination before new animal are introduced, it is difficult to assess the origin of this infection.

Symptomless sows that are *Salmonella* carriers and occasionally excrete *Salmonella* may constitute a hidden but substantial risk for all pigs in the same epidemiological unit. As such, they may also spread *Salmonella* through the piglets to other herds, the risk being even more obvious at the satellite pig houses between which the intermittently shedding carrier sows circulate. Carrier sows may thus act as a significant source of infection by maintaining *Salmonella* infection in the herd and for infecting the piglets that, following weaning, are transported to slaughter pig units.

Due to the rather high average prevalence of *Salmonella*-positive holdings with breeder pigs (31.8%) as reported in the baseline study (EFSA, 2009a), the control measures should have a long term perspective.

BIOHAZ Panel's answer to the terms of reference 7

Breeder pig herd prevalence is a major determinant of slaughter pig lymph node prevalence at EU level. The importance appears to be more obvious in high prevalence countries as a 90% reduction of the breeder pig herd prevalence could theoretically result in a reduction in an order of magnitude of two thirds of slaughter pig lymph node *Salmonella* prevalence.

6.3.2. Expected reduction of *Salmonella* prevalence in slaughter pigs by reduction of prevalence in breeder pigs

Terms of reference 8

A quantitative estimation at Community level is requested of

The expected reduction of *Salmonella* prevalence in slaughter pigs (based on bacteriology in lymph nodes or serology at slaughter) by a reduction (e.g. 5- or 10-fold) of *Salmonella* prevalence in breeder pigs.

Quotation from the QMRA report

See answers to terms of reference 7 (chapter 6.3.1)

BIOHAZ Panel answer to the terms of reference 8

See answers to terms of reference 7 (chapter 6.3.1)

6.3.3. Sources of infection for breeder pigs at farm level

Terms of reference 9

A quantitative estimation at Community level is requested of

The sources of infection for breeder pigs and piglets at farm level.

This was outside the terms of reference for the QMRA.

Remarks

The sources of infection of the breeder pig units are principally the same as for the slaughter pigs described above (chapter 6.1.3).

The major sources for introduction of *Salmonella* to a *Salmonella*-free breeder pig herd are the infected pig and contaminated feed.

In the case of herds having an integrated (farrow-to-finish) slaughter pig production, the piglet production may not always be sufficient for filling the finishing sections of the pig herd. In order to fill the finishing sections pig farmers have to purchase weaned pigs from other herds. In this scenario, incoming pigs if originating from herds with *Salmonella* will be an important source for *Salmonella* in the integrated herd.

The same sources apply for herds already harbouring *Salmonella*-infected animals and with *Salmonella* contamination of the internal environment. In these herds the infected pigs and the internal environmental contamination are the major sources for infection of *Salmonella*-free replacement animals, thereby keeping *Salmonella* infections circulating in the herd.

BIOHAZ Panel answer to the terms of reference 9

The major sources of infection for breeder pigs are the same as for slaughter pigs; infected incoming pigs and *Salmonella* contaminated feed.

There are also other external and internal sources as described for slaughter pigs

Note that the breeding pyramid has not been modelled.

6.3.4. Reduction of prevalence in breeder pigs by control measures

Terms of reference 10

A quantitative estimation at Community level is requested of

The reduction of the prevalence in breeder pigs and piglets by the most important potential treatments or control measures at farm level;

This was outside the terms of reference for the QMRA

Remarks

Measures to control *Salmonella* in breeder pigs are mainly the same as for slaughter pigs (answer to TOR 4). In addition, special attention has to be paid to the fact that the mean life span of breeding

sows is far longer than for slaughter pigs. Sows can be kept for several parities before being culled and thereby, despite an annual average turnover of 30-50%, represent a potential reservoir of *Salmonella* in the herds.

A strict all-in/all-out system (a "one-way itinerary", without cross-roads) with pigs remaining the same in each group all along the post-weaning and growing-finishing stages can be applied for the offspring. On the contrary, the sows are moving on the farm according to the reproduction cycle. Even if batch-farrowing is applied, the sows from different subsequent batches come in contact especially during the breeding period or during pregnancy.

The knowledge of the *Salmonella* status of incoming replacement breeding stock is of utmost importance and, where possible, introduction of new stock should be done batch wise following a quarantine procedure. The way to properly handle *Salmonella* infection in sow herds raised in groups will need care, especially in large farms. Since the piglet is bacteriologically sterile at birth, the cleanliness of the environment around the neonate is of paramount importance in the farrowing rooms, to reduce the risk of an early infection.

Thus, a primary step is to know the infection (*Salmonella*) status of a farm. Methods for this are not standardized but are preferably based on bacteriological investigation of pooled (by group of animals in pens) faecal samples (EFSA, 2006). Herds found not to be infected could maintain that status through the use of basic biosecurity measures and efforts to prevent the introduction of infected pigs. This can be achieved by introducing pigs only from those herds found to be free from *Salmonella* or from herds with the same or higher *Salmonella* status.

When a farm is found to be infected, the strategy for control measures needs to be applied on a case by case basis. No single methods or "silver bullet" are at hand and the efforts to reduce the prevalence of *Salmonella* infection require a long term perspective, in particular in larger farms. Those methods, found to be effective for *Salmonella* infections in other animal species (Wierup, 1994), but also for the control of other infectious diseases in pigs, could be applied.

Despite the socio-economic (e.g. farm size and industry structure) and the epidemiological context showing little similarity with other MSs, the long term experiences from the low prevalence countries of Finland and Sweden have demonstrated that simple control methods can be applied successfully, at least for small breeding herds A first step is to evaluate to what extent the farm is infected and then to repeat the sampling procedure at intervals of one to two months. In addition to the testing it is essential to improve and optimize hygiene and biosecurity and to prevent introduction of *Salmonella*, primarily through incoming infected animals. If the infection initially is limited to certain compartments of the herd, directed actions can be taken through isolation or separate management. If only few pigs are found to be infected, they can be eliminated by slaughter, but the choice of such a strategy must be based on foreseen likelihood of success and cost efficiency. Experiences from Sweden in pigs but also in cattle, show that the number of excreting animals decreases by time and those repeatedly found infected have to be slaughtered (Wierup, 1997).

An important knowledge gap is the lack of experience from *Salmonella* reduction or elimination in large herds with high levels of *Salmonella* contamination. In particular, knowledge about the efficacy of interventions or combinations thereof is needed, as alternative strategies to stamping out. It is suggested that trials with the implementation of the above or other interventions are evaluated in field studies. Such field studies are urgently needed. In heavily infected breeding herds the strategy probably needs to be applied on a long term basis and not by initial direct application of test and slaughter.

It is logical to assume that a significant proportion of the non shedding animals still may be infected, but they are supposed to control infection and shedding as a result of immunity. As described for the slaughter pigs (chapter 6.1.4) it is essential to maintain a good health status and avoid stress to reduce the risk that chronically infected animals will start to shed *Salmonella*.

An overall strategy for the reduction of *Salmonella* in breeding herds and slaughter pigs needs to consider the use of a top down approach that successfully and logically has been applied for control of *Salmonella* in poultry, as well as for other infectious diseases in pigs and other food animals. Efforts should therefore be made to control and if possible to eliminate *Salmonella* infection from the elite breeding (nucleus) and multiplier herds to the extent possible.

In addition to on farm *Salmonella* reducing control measures for feed (chapter 6.1.4), special focus needs to be directed also to crushing plants and feed mills aiming at the elimination of *Salmonella* from feed ingredients and feed as previously addressed by EFSA (2008c).

It also needs to be emphasized that because the risk for exposure of *Salmonella* cannot be eliminated, biosecurity measures and surveillance for *Salmonella* must continue after a *Salmonella*-free or low prevalence status have been achieved.

BIOHAZ Panel answer to the terms of reference 10

It is not possible to give a simple quantitative estimate at the EU level.

Salmonella control in breeder pig farms need to focus on the following key control measures:

- Control of *Salmonella* in nucleus and multiplier herds
- Control of *Salmonella* in incoming pigs (knowledge of *Salmonella* status)
- Control of *Salmonella* in feed
- Biosecurity programs should include the control of *Salmonella*

CONCLUSIONS

TOR 1: A quantitative estimation at Community level is requested of the relative contribution of *Salmonella* infections in slaughter pigs on *Salmonella* cases in humans. If an estimation of the influence of the prevalence of *Salmonella* in pigs at slaughter on human cases is not possible within the indicated time schedule, the influence on *Salmonella* prevalence in pig meat at retail should be estimated

- The fraction of human salmonellosis cases attributable to *Salmonella* in pigs and pig meat will vary considerably between MSs and will mainly depend on i) the *Salmonella* occurrence (prevalence and numbers) in pigs and pig meat, ii) consumption patterns and preferences and iii) the relative importance of other *Salmonella* sources. Differences in the quality and sensitivity of the human reporting systems and testing methods between MSs make direct comparison of surveillance results between MSs difficult.

- From the descriptive and comparable analysis of the serovar distribution in animal sources and humans, a cautious assessment would be that around 10-20% of human *Salmonella* infections in EU may be attributable to the pig reservoir as a whole. However, the use of this estimate necessitates caution due to the lack of MS-specific data on the distribution of serovars in humans.

TOR 2: A quantitative estimation at Community level is requested of the expected reduction of *Salmonella* cases in humans (or pig meat at retail) by a reduction (e.g. 5- or 10-fold[29]) of *Salmonella* prevalence in slaughter pigs (based on bacteriology in lymph nodes or serology at slaughter)

- It appears that an 80% or 90% reduction of lymph node prevalence should result in a comparable reduction in the number of human cases attributable to pig meat products.

TOR 3: A quantitative estimation at Community level is requested of the sources of infection for fattening pigs at farm level

- Theoretically, according to the QMRA the following scenarios appear possible:

  - By ensuring that breeder pigs are *Salmonella*-free a reduction of 70-80% in high prevalence MSs and 10-20% in low prevalence MSs can be foreseen;

  - By feeding only *Salmonella*-free feedstuffs reduction of 10-20% in high prevalence MSs and 60-70% in low prevalence MSs can be foreseen;

  - By preventing infection from external sources of *Salmonella* (i.e. rodents and birds) a reduction of 10-20% in slaughter pig lymph node prevalence can be foreseen in both high and low prevalence countries;

TOR 4: A quantitative estimation at Community level is requested of the reduction of the prevalence in slaughter pigs by the most important potential treatments or control measures at farm level

- To achieve control of *Salmonella* in slaughter pigs the two major sources should be controlled:

  - *Salmonella*-infected breeder pig herds and

29 Interpreted as 80% or 90% reduction

- *Salmonella*-contaminated feed

- The maximum impact of achieving control of these two sources is shown in the answer to the terms of reference 3.

- Eliminating those sources may not be practically achievable. Nevertheless, all efforts have to be directed at reducing the prevalence in breeder herds and the *Salmonella* contamination of feed, so as to minimize infection in slaughter pigs.

- Beside these sources there are several other sources of infections in slaughter pigs, namely internal and the external environment such as other farm animals on the premises and wildlife.

- Effective implementation of biosecurity measures (e.g. age- and source-segregated rearing including cleaning and disinfection procedures between batches) and GHP/GMP are important for becoming and remaining a *Salmonella* low risk holding.

- In MSs with high prevalence in breeder and slaughter pigs, control of *Salmonella* in breeder pig herds can be the first step to control *Salmonella* in slaughter pigs.

- Measures to increase the pig's resistance towards *Salmonella* infections include change of feed type and/or vaccination.

- General *Salmonella* control measures should always be applied, but where the particular emphasis shall be placed will depend on the epidemiological situation of the herd.

- A hierarchy of control measures is suggested - a high prevalence in breeder pigs needs to be addressed first, followed by control of feed and then control of environmental contamination.

TOR 5: A quantitative estimation at Community level is requested of the impact of transport, lairage and slaughter process on contamination of carcasses

- Unhygienic practices enabling direct and/or indirect faecal contamination during transport, lairage and, particularly, slaughter and dressing, increase the risk of carcass contamination with *Salmonella*. Due to insufficient quantitative data on the microbial load of *Salmonella* on the skin, it was not possible to quantify the effect of cross-contamination during transport and lairage. During slaughter and dressing, the evisceration step was found to be a critical procedure for cross-contaminations and thus for the *Salmonella* occurrence on carcasses.

TOR 6: A quantitative estimation at Community level is requested of the expected reduction of *Salmonella* cases in humans (or pig meat) by the most important potential control options during transport, at lairage or during the slaughter process

- For each MS, a reduction of two logs (99%) of *Salmonella* numbers on contaminated carcasses would result in more than 90% reduction of the number of human salmonellosis cases attributable to pig meat consumption. A reduction of one log (90%) would result in more than 80% reduction of human cases.

- This could be achieved through measures preventing direct and/or indirect faecal contamination during transport, lairage and, particularly, slaughter and dressing processes; and/or by effective carcass decontamination.

Multiple interventions in the food chain

- Beyond compliance with EU legislation and GMP/GHP, it appears that control of *Salmonella* in pig meat as a public health problem should be based on the individual MSs situations and include combinations of following interventions: *Salmonella*-free (low risk) breeder pigs, *Salmonella*-free feed, cleaning-disinfection between batches both on-farm and during lairage, avoidance of faecal contamination during slaughter and decontamination of the carcasses. Efficient vaccination will also be useful to control *Salmonella* on farm, but might interfere with the interpretation of serological test results in monitoring/surveillance programmes. The QMRA results could give some guidance on appropriate combinations.

- From the current evidence, it would appear that specific slaughterhouse interventions are, at present, more likely to produce greater and more reliable reductions in human illness, at least in a shorter timeframe than can be achieved at the farm in high prevalence MSs. However, the hypothetical reductions and multiple interventions investigated with the current risk assessment model suggest that MSs can achieve more effective reductions in human cases by targeting both farm and slaughterhouse.

TOR 7 and 8: A quantitative estimation at Community level is requested of:

- **The relative contribution of *Salmonella* infections in breeder pigs on *Salmonella* prevalence in slaughter pigs (based on bacteriology in lymph nodes or serology at slaughter).**

- **The expected reduction of *Salmonella* prevalence in slaughter pigs (based on bacteriology in lymph nodes or serology at slaughter) by a reduction (e.g. 5- or10-fold) of *Salmonella* prevalence in breeder pigs**

  - Breeder pig herd prevalence is a major determinant of slaughter pig lymph node prevalence at EU level. The importance appears to be more obvious in high prevalence countries as a 90% reduction of the breeder pig herd prevalence could theoretically result in a reduction in an order of magnitude of two thirds of slaughter pig lymph node *Salmonella* prevalence.

TOR 9: A quantitative estimation at Community level is requested of the sources of infection for breeder pigs and piglets at farm level

- The major sources of infection for breeder pigs are the same as for slaughter pigs; infected incoming pigs and *Salmonella* contaminated feed.

- There are also other external and internal sources as described for slaughter pigs

- Note that the breeding pyramid has not been modelled.

TOR 10: A quantitative estimation at Community level is requested of the reduction of the prevalence in breeder pigs and piglets by the most important potential treatments or control measures at farm level

- It is not possible to give a simple quantitative estimate at the EU level.

- *Salmonella* control in breeder pig farms need to focus on the following key control measures:

  - Control of *Salmonella* in nucleus and multiplier herds

  - Control of *Salmonella* in incoming pigs (knowledge of *Salmonella* status)

- Control of *Salmonella* in feed
- Biosecurity programs should include the control of *Salmonella*

General conclusions:

- This QMRA represents a major step forward in terms of modelling *Salmonella* in pigs from farm to consumption as it takes into account the variability between and within EU MSs. Transmission of *Salmonella* was analysed using the individual pig as the unit of interest.
- There are data gaps and critical assumptions in the model, and these were carefully considered when interpreting the results of the model. Due to necessary simplifications in the model, some interventions could not be considered. Therefore additional strategies to those listed above could contribute to control *Salmonella* in pigs (e.g. feed formulation) but their impact was not quantified and they are not discussed in the present opinion.
- Setting prevalence targets for *Salmonella* in slaughter pigs based on the clustering of Member States as used in this QMRA and this opinion is neither recommended nor intended.
- The uncertainty analysis presented in the QMRA report can be considered as a sensitivity analysis for the whole model. The full effect of suggested control measures can probably be evident first after several years (5-10 years). However at the herd level certain measures might have impact in the short term such as change of feed type, increased biosecurity, and on-farm hygiene.
- Carcass decontamination at pre-chilling stage in the slaughterhouse is currently being used in some countries and can be considered as an addition to preventive measures implemented at the earlier steps of the food chain.
- Combinations of control measures can have synergistic effects and the choice is preferably best made based on the individual pig herd's and MS's situation.
- The control of *Salmonella* in pig reservoir in the EU is a reasonable objective.

RECOMMENDATIONS

- MSs should have the possibility to assess their national pig meat food chains using this QMRA model.
- Due to a lack of experiences in *Salmonella* reduction in large herds with a high level of *Salmonella* contamination, field trials of possible interventions are urgently required.
- The ecology of *Salmonella* at the pre-harvest stage should be analyzed with the goal of understanding the *Salmonella* population dynamics and thereby identify the most relevant actions to be implemented according to the epidemiological farm profiles, so that the low-risk status can be attained by pig holdings.
- The slaughterhouse remains a critical step of the pig meat chain in respect to pig and carcass contamination and numerous aspects still remain unknown. Therefore studies need to be performed to properly assess the ways carcasses become contaminated.
- The airborne transmission of *Salmonella* in the abattoir should be paid more attention.

- In order to obtain more reliable estimates for the importance of different sources to human salmonellosis in the EU, it is required that available data are shared both at national and Community levels.

- In future QMRAs it is recommended to include methodologies to assess the quality of the data used as well as the quality of the assumptions.

- Criteria for assessment of relative importance for human health of the individual *Salmonella* serovars in the different stages of the food chain should be applied to pig meat.

- The EU *Salmonella* control strategy in pigs should be continuously evaluated to identify possible improvements.

- More data on consumer behaviour (transport from retail to home and storage at home) are needed to model possible growth of *Salmonella* in pig meat.

- To reflect the EU situation, data on trade of pig meat, pig meat products and live pigs within the EU are needed. Availability of these data would allow further development of this QMRA model in order to account for the impact of import and export and intra community trade.

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APPENDICES

A. SUGGESTIONS FOR CONTROL MEASURES

At pre-harvest stage: Breeder pigs

General considerations

- The strategies to be applied for control measures need to consider that the occurrence of *Salmonella* in pigs is a result of a bacterial infection, with the oral-faecal route as the predominant route of transmission.

- *Salmonella* control policies should have a more regional or MS-specific approach in order to achieve those levels of *Salmonella* reduction as described in the QMRA report.

- To achieve a reduction of *Salmonella* infection in breeder pigs and subsequently in slaughter pigs and a reduction in human illness attributed to pig meat, a long term implementation of multiple control measures is required. The full effect of control measures may be seen after several years (5-10 years).

- Effort should be directed to prevent introduction of *Salmonella* through the feed.

Specific considerations

- Despite the fact that socio-economic (e.g. farm size and industry structure) and the epidemiological context show little similarity with other MSs, the long term experience from low prevalence countries indicates that control measures can be applied and some have been found to be effective to control *Salmonella* infections in pigs as well as other animal species.

- Because the risk of exposure of the feed production chain cannot be eliminated within the foreseeable future, HACCP-based surveillance and associated control measures must be in place also when low prevalence has been achieved.

- A primary step is to find if, and to what extent, individual farms are infected, preferably by the use of bacteriological investigation of faecal samples in a harmonised and validated sampling scheme.

- For farms found not to be infected, efforts should be directed to maintain that status, in particular avoiding the introduction of infected pigs. Generally, pigs should be introduced only from herds from the same or better *Salmonella* status.

    - When a farm is found to be infected, no single control measure is readily available for elimination of the infection. The control interventions should focus on improving the biosecurity and optimizing the hygiene. If the infection initially is limited to certain compartments of a farm, directed actions can be taken through isolation or separate management internal biosecurity.

    - In order to avoid chronically infected animals shedding *Salmonella* it is important to maintain a good health status and avoid stress.

    - Age-segregated rearing, batch production, strict all-in/all-out management are essential to improve health status and thereby to prevent *Salmonella* transmission.

- Priority should be given to the control of *Salmonella* at nucleus farms.

At pre-harvest stage: Slaughter pigs

- Feed is an important source of *Salmonella*. Some of the feed ingredients used are particularly exposed to *Salmonella* contamination. Better detection methods are needed, and the information obtained in this respect should be made available.

- HACCP and other procedures aiming at a better control of contamination throughout the feed chain should be encouraged. GMP and GHP should be ensured in industrial manufactures as well as on farms where home-mixed feeds are prepared.

- When feed ingredients or compound feeds are contaminated by *Salmonella*, appropriate treatments should be applied. However this issue needs further research in order to assess improved valuable options to the current methods.

- After delivery (compound feed) or after on-farm preparation, the storage conditions should avoid contamination of the feed from the environment (such as from birds, rodents…).

- Liquid feeding tends to reduce *Salmonella* shedding by fattening pigs when compared to dry feeding. It can be recommended as far as practical means allow it. The inclusion of specific compounds in the diet such as organic acids could also help.

- Beyond feed, pigs can get exposed to *Salmonella* through a number of other routes: drinking water, rodents, birds, poorly cleaned and disinfected trucks. Farmers and stockpersons can also be vectors of *Salmonella*. Particular awareness about external biosecurity and compliance to the rules are both required.

- Since live pigs are frequent healthy carriers of *Salmonella*, transparency on *Salmonella* status of the herds supplying pigs is critical for successful prevention. The point needs to be considered when pigs are transported for breeding purpose in order to avoid cross-contamination.

- Herd managers should strictly implement age-segregated rearing with an all-in/all-out hygiene policy. In-between batches of pigs, the entire space (i.e. room, compartment, building…) should be thoroughly cleaned, disinfected, and left empty for drying before restocking again (e.g. 3 day of down time). Mixing unacquainted pigs should be discouraged and limited to the necessary, since it generates fighting and stress that thereby increases *Salmonella* shedding from infected pigs. In fattening units where piglets are purchased from different farms, traceability should be combined with transparency. The incoming pigs should preferably populate separate rooms based on their origin, especially when the *Salmonella* status differs between provider farms.

- At the farm stage, a specific effort should be directed at maintaining the pigs clean, thus reducing the oral-fecal cycles.

- Different diseases affecting the grow-finishing pigs, mainly of enzootic nature such as respiratory or digestive disorders often lead to oral treatments. They often result in an increased risk of *Salmonella* fecal excretion in contaminated pigs. Special care is recommended to offer the pigs an adequate environment, meeting their needs in terms of housing, feeding, hygiene and general husbandry so as to reduce the impact of those multifactorial production diseases and reduce drug use.

- The use of antimicrobials for *Salmonella* control in pigs should be avoided.

- When an on-farm lairage is used before shipment to the slaughterhouse the place has to be thoroughly cleaned and disinfected immediately after pig departure.

At harvest stage

- It is essential to establish measures to prevent/reduce meat contamination at pig slaughterhouses based on GHP and HACCP principles including limitation of the level of contamination of the animals or their intensity of excretion of *Salmonella* at the end of the fattening phase.

- The trucks and trailers transporting pigs should be thoroughly cleaned and disinfected as soon as the pigs are unloaded at the slaughterhouse. The vehicles should be dry before the start of loading pigs again. The drivers should adhere to the biosecurity rules when loading pigs.

- Separate transport, lairage and slaughter depending on the farm status (i.e. logistic slaughtering) can avoid cross-contamination and can help maintaining pigs/carcasses *Salmonella*-free.

- At the slaughterhouse, the size of the lairage pens should be such that commingling of unfamiliar pigs is avoided, hence avoiding unnecessary fighting and stress.

- The floor of the lairage pens should be maintained clean and well-drained. Fully slatted floors favor cleanliness. After depopulation, the pens have to be thoroughly cleaned so as to eliminate all faecal material. At the end of the day they have to be properly disinfected and let to dry before restocking.

- The pigs should be clean when entering the stunning system as well as when they come out of it. When a CO_2 stunning is used, care is recommended so as the skin does not get fouled in the CO_2 chamber.

- Scalding is a critical step regarding skin contamination. Clean pigs should enter the scalding tank and in this respect pre-washing might be useful. The temperature of the water should be maintained at the required level (i.e. 60-62°C) and the water tank has to be emptied and cleaned at the end of the workday. An alternative to the water tank is the application of hot steam. The latter system is used to clean the skin and to prepare it for dehairing.

- Double singeing can help reduce skin contamination. The flame should efficiently reach the entire surface of the body.

- The slaughter line should clearly separate the “slaughter area” (i.e. during and before belly opening) from the “carcass area” (after opening). Air flow and equipment functioning should be such that aerosol production is limited and thereby the carcasses get less exposed to contamination.

- Evisceration remains a critical step regarding hygiene since bowel laceration can occur. A specific awareness about risk of fecal leakage and microbial aerosols formation from such accidents is recommended. This step of the slaughter line should be handled such as the risk of contamination is minimized.

- The slaughter processing machinery should be maintained clean. Systems able to properly decontaminate the material coming in physical contact with the carcass (i.e. at cutting the breast bone, at pluck removal, at splitting or at trimming) should be encouraged.

- At the end of each workday, all the equipment needs to be thoroughly cleaned and disinfected. Residual *Salmonella* contamination on the material coming in touch with the skin or with the meat is to be avoided.

- An important knowledge gap is about the most effective clean-up procedure in heavily infected breeder herds, apart from stamping out.

- Different methods aiming at carcass decontamination at the end of the slaughterline (before chilling) offer the potential to reduce bacteria from the surface. Promising methods are currently under evaluation. Further research should consider eventual detrimental side effects such as an increased tendency for those treated carcasses to become re-contaminated at later stages.

B. TECHNICAL MODEL

Table 2: Farm module

Inputs (V: variable, C: constant)	Model brief description	Units of concern	Outputs	Assumptions/limitations
8 Farm types defined by the combinations of size(small/large), Feed (wet/dry), Floor (slatted/solid), management of animal flow (AIAO/Continuous), outside/inside, and production stage of animal (breeder-finisher/breeder-weaner/grower-finisher) Weight of each type depends on the MS's Number of animals per pen/room/building (C) Age at weaning, Growing and finishing period: specific to large and small farms (C) *Salmonella* introduction: via animals (Sow: herd prevalence (C) for each MS, animal prevalence same for the 4 MS), feed (V) (same probability of feed lot contamination and same distribution of concentration in feed) and rodent (V) *Salmonella* transmission between animals: Via fecal materials (V) and feed (V) Amount of available fecal material dependent on flooring type. Piglets ingest from 0 to 21 g of fecal material/day and w/g/F 0 to 100g/day Probability of infection is derived from a dose response model Variable duration of shedding per animal	Dynamic model including random opportunities of *Salmonella* introduction and transmission to pigs during a period of 500 days 48 types of large farms 8 types of small farms 1,000 farms were allocated to the 56 farm types. Each large farm produces 72 batches to send to the slaughterhouse Each small farm produces 3 batches to send to the slaughterhouse	Farms Pens Batches Pigs within 72 batches	Status of Pigs within batches to send to slaughterhouses for the 1,000 simulated farms over 500 days of farm production: Lymph node Infection status Concentration of *Salmonella* in fecal material Outputs presentation: In addition to the graphs a table is needed to give proportion of batches with zero positive *Salmonella* animals and distribution of animal prevalence within infected batches (mean, std, intra-class correlation, percentiles...)	Farm type definitions and their distribution in the 4 considered MSs Feed: influences response to exposure. Breeding herd prevalence: is taken from EFSA breeding pig survey and assumed to be constant within each MS. The number of farms positive for *Salmonella* varies between groups or type of farms within each MS and during time. Ignoring this variability is equivalent to assume that the spread of *Salmonella* in MSs is random and no risk factors at farm level exist. In addition, farmer applying good practices choose the origin of introduced animals…. The probability of the breeding herd being positive was assumed to be independent to the defined 56 farm types Transmission between animals is mainly from ingested fecal material: the module assumes homogenous mixing of fecal material and *Salmonella* contamination. *Salmonella*s are treated equally: same dose-response model, same survival and dissemination in farm environment… Model use Although the model does output an estimate for the pig prevalence it is not the best tool for this as its main aim was to assess the relative effect of interventions. . However, it could be thought as a tool to experiment virtually some intervention measures with the assumptions that the non considered factors in the model will not modify the effect of the control measures (possible interactions)

Table 3: Transport and lairage module

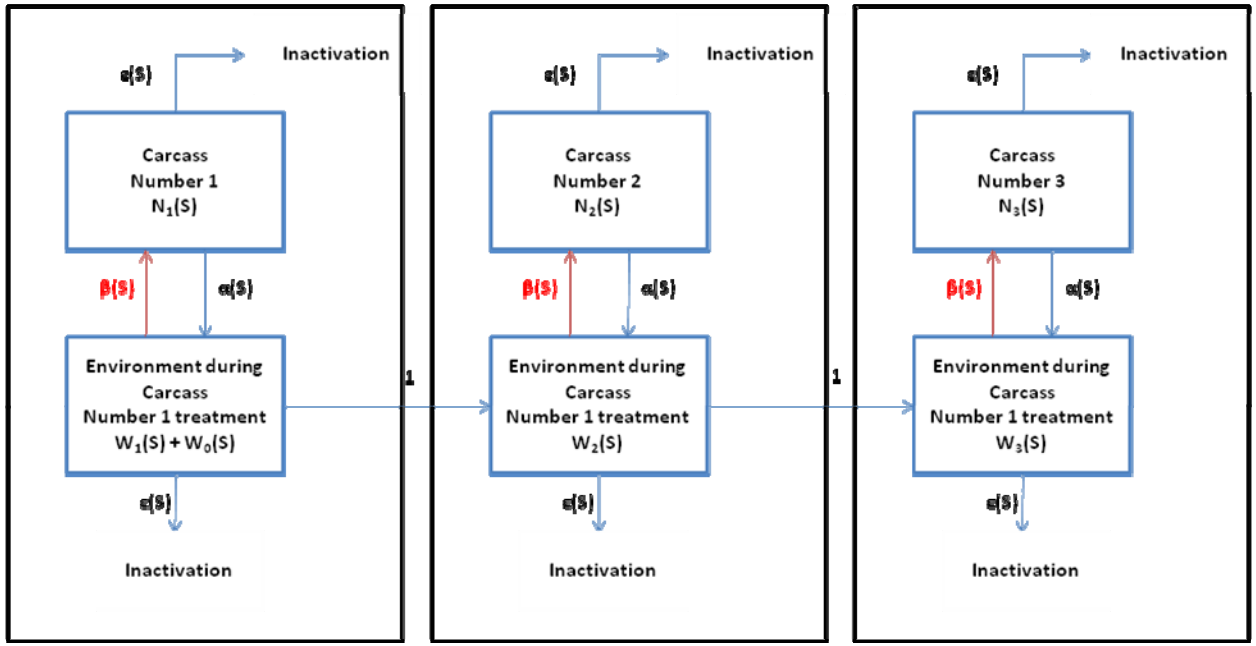
Inputs (V: variable, C: constant)	**Model brief description**	**Units of concern**	**Outputs**	**Assumptions/limitations**
Prevalence of *Salmonella* positive animals and concentration in fecal material: Outputs from Farm module (V) Number of slaughtered animals per day: small vs large, (V) for MS1, MS2 and MS3; low numbers and (C) for MS4 Frequency and amount of fecal material shed by pigs during transport (V) Maximum amount of ingested faecal material per hour (C) Probability of infection is derived from a dose response model Probability of stressed animals during transport (C) Number of pigs per pen (V) Number of pens per truck is adapted to batch size Parameters describing the truck contamination and cleaning efficacy Duration of transport (V) MS1: Based on expert opinion – between 0.5 and 8 hours; mean 2.1 hours. MS2&4: Based on MS2 transport data; between 0.3 and 11.6 hours, mean of 1 hour (Figure 8.4 in QMRA report; pg. 174). MS3: Between 0.7 and 10 hours, mean of 3.85 hours. Transport between MSs is not considered Lairage capacity MS2 data (V) Number of animals per pen: 50 Stocking density of pigs: MS2 data (V) Time spent in lairage: MS2 data (V) with	Dynamic transmission model Between animals in the same pen From truck or lairage environment carried-over fecal material Batches to enter the transport module are randomly selected from the farm module outputs. There is no mixing of animals from different farms. Although this assumption was investigated (within the intervention analysis) and found to have little effect.	Lymph-node positive status of pigs within farm batches	Number of *Salmonella* in the gut of individuals pigs Concentration on the hide Output data sorted in the order that the pigs enter the slaughter process In addition to the graphs and tables showing the increase of the overall animal prevalence during transport and lairage, it will be interesting to have the distribution of change ratio per batch..	Pigs from large farms will go to large slaughterhouses and pigs from small farms will go to small slaughterhouses No direct contact between animals coming from different farms. However, in lairage pigs from previous batch may contaminate the environment for future batches No cross contamination between animals belonging to different pens Surrogate data from other MSs for transport and lairage conditions when data unavailable Surrogate data for *Salmonella* persistence in trucks and lairage environment: E. coli data

distinction of day and overnight kept Parameters describing the lairage contamination and cleaning efficacy: MS2 data (V) Hide contamination parameters (V)				

Table 4: Slaughterhouse

Inputs (V: variable, C: constant)	Model brief description	Units of concern	Outputs	Assumptions/limitations
Outputs of transport & lairage module: i.e. a table including animal status infected (lymph-node positive)/non infected concentration in fecal material and hide contamination. For each of the following slaughterhouse stages: 1) scalding, 2) dehairing, 3)singeing, 4) polishing, 5) belly opening, 6) splitting, 7) trimming, a set of parameters was assessed: Transfer rate of *Salmonella* from carcass to the carcass environment Transfer of *Salmonella* from carcass environment to the carcass Time spent in machine. Possible Inactivation parameter Scalding: Water temperatures are assumed (V), European guide range for MS1, MS3, MS4 and observed data from MS2. Time spend in the scalding bath (C) for MS1, MS3, MS4 and (V) for MS2. Transfer parameters from E. coli/chicken skin data. Dehairing: same data are used to assess the distribution of time spend in the dehairing machine (MS2 study) Transfer parameters assessed using Literature and fit to data. Singeing: inactivation using pig data on *Enterobacteriaceae* decrease during singeing… Polishing: time spend in polishing machine derived from Belgium study (V). Transfer parameters estimate are not well explained… Belly opening: No direct estimate of transfer parameters at this stage. Splitting: cross contamination from steel: same as in the previous stage…Transmission data from stainless steel to sponges used as substitute. Trimming: based on the sensitivity of the inspection to detect fecal contamination… Blast chilling: expert opinion. One log reduction	Dynamic transmission model of *Salmonella* from carcasses to carcasses via environment/equipment Three microbiological processes: inactivation, partitioning and cross-contamination with the environment	Pig at the start of the slaughter line Carcass Half carcass	Number of *Salmonella* per half carcass The output presentations don't help to understand the model behavior. Only the average output is presented. There is no longer the concept of batches, only individual pigs in the slaughterline	The model assumes absence of contamination in the environment at the starting point although contamination at start of day due to incomplete cleaning can be turned on in the model. The main sources of *Salmonella* are the slaughtered animals House flora was assessed with very limited data: assumption all the carcasses will receive a certain amount of *Salmonella* from the slaughterhouse environment→100% of the half carcasses are contaminated but at a very, very low level. Transfer parameters estimates represent a high uncertainty. The sensitivity analysis is different from one MS to another: surprising when the majority of model parameters are equal.

Figure 5: Slaughterhouse model



….. until the last carcass.

Slaughterhouse stage model: for each stage (S) the model consider two compartments carcass with a number of *Salmonella* N and environment with a number of *Salmonella* W. The model describes the transfers from one compartment to another, possible inactivation and the contamination of the environment from previous carcasses.

Table 5: Cutting plants

Inputs (V: variable, C: constant)	**Model brief description**	**Units of concern**	**Outputs**	**Assumptions/limitations**
Outputs from previous module: Number of *Salmonella* per half carcass Portion size: (C), same sizes for MS2 and MS1, same sizes for MS3 and MS4.	Combines the half-carcasses from large and small slaughterhouse and allocate them randomly to the three considered products Consider the cross-contamination during cutting: 5 type of cuts are defined (1: at slaughterhouse, 2: primal cuts, 3 & 4: secondary or retail cuts and 5: tertiary cuts).	Half-carcass portion	Relative *Salmonella* densities per region of cuts (9 type of pieces: A to I) For each products: 10 000 portion concentrations are simulated	*Salmonella* is uniformly distributed over the carcass surface Minced meat is produced from the same half carcass

Table 6: Preparation and consumption module

Inputs (V: variable, C: constant)	Model brief description	Units of concern	Outputs	Assumptions/limitations
Output from the previous module: number of *Salmonella* per portion of pig meat cut, minced meat and minced meat for sausage production. Transport and retail: Temperature and duration, same data are used for the 4 MS. Temperature in lorries from French study (V). Duration (C): 110 h (5 transport, 9 wholesale, 96 display cabine) Consumer transport and storage Travel time from store to domestic (V) same distributions for MS1, US and MS3. MS4 distribution from Finnish data. Storage time in the consumer refrigerator (V) same distribution for the 4 MS, data from MS2. Temperature during transport (V), distribution for the first 3 MS using French data and for MS4 using data from Finland. For fridge temperature (V) using MS2 data. Cross contamination parameters: from meat to hand, from hand to meat, from meat to board, from board to lettuce were taken from one published study. For the Pig meat cuts the cross contamination is more complex including: pig meat meat, knife, chopping board, hands, tap and salad. The parameters estimates are based mostly on literature and where lacking on expert opinions. Growth inactivation: *Salmonella* generic growth and inactivation parameters in meat were used (data from ComBase) Cooking of hamburger patties: thermodynamic model was used. Cooking times (V), normal distribution with 95% of values from 8 to 15 minutes. Dry Cured Sausage Target water activity was 0.9, pH less than 5.3. three stages were defined: salting, fermentation, drying and storage. A growth/no growth interface were assessed predicting log increases based on growth curve fit to many published studies.	Three sub-modules: pig meat cuts, minced meat and fermented sausage. Dynamic model including possible growth, inactivation and cross-contamination	Consumer portion	Number of directly ingested *Salmonella* per consumed portion of pig meat products or indirectly via contaminated salad.	Data gaps on temperature and duration during transport and storage at distribution, retail and consumer level. Data gaps on the description of meat handling and preparation Salad preparation assumption

C. ERRATUM TO FINAL REPORT

Submitted: 19th October 2010

EFSA *Salmonella* in Pigs QMRA Consortium:

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1. Introduction

During the preparation of scientific papers resulting from the EFSA Quantitative Microbiological Risk Assessment (QMRA) for *Salmonella* in Pigs (EFSA, 2010a) three errors were identified. These are:

1. Within the Preparation & Consumption module of the QMRA, the travel time for consumers, from the store to the domestic home for MS4 only, was too high. This was a consequence of a unit error (i.e. confusion of minutes and hours). The effect of this error on the conclusions of the QMRA and the associated scientific opinion (EFSA, 2010b) are provided in Section 2.

2. Within the Intervention Analysis (Chapter 13) an erroneous placement of a graph in the intervention analysis chapter was identified (Figure 13.4, page 357). The graph currently presented presents a post-dehairing intervention, when it should present a pre-chill intervention (as denoted in the Figure text). The effect of this error on the conclusions of the QMRA and the associated scientific opinion (EFSA, 2010b) are provided in Section 3.

3. Further analysis of the interventions has shown that the result for cleaning and disinfection (C&D) is unreliable (Figure 13.5) as additional model runs were required for convergence. The impact of this on the conclusions of the QMRA and the associated scientific opinion (EFSA, 2010b) are provided in Section 4.

For each of these errors, this erratum provides a description of the impact of the errors on the results and conclusions of the QMRA and also where the final report (EFSA, 2010a) has been amended to rectify the situation. Accompanying this erratum is a second version of the EFSA QMRA for *Salmonella* in Pigs report, detailing all changes made and also a clean copy.

The QMRA consortium is very disappointed that these errors were made, but it is important to note the difficulty in validating and checking a model of such size and complexity. The model consists of upwards of 100,000 lines of code and 150 parameters for each MS case study; along with generic model parameters, in the region of 900-1000 parameters were estimated. Mistakes are probably inevitable in a model of this complexity. However, we believe that this risk is outweighed, in this project, by the benefit of providing a generic model for the EU, capable of analysing the effect of a number of interventions. Recognising this, every effort was made in order to minimise the risk of such errors occurring and a long process of review was carried out, including:-

- Sharing/reviewing of models between the modellers at VLA, RIVM and Food-DTU.
- Modelling meetings throughout the duration of the project to discuss design, parameterisation and outputs of the model.
- Full project team review of the draft and final report. Including a review by internal reviewers with expertise in mathematical modelling/risk assessment. It was during this process that the overestimation of number of cases from MS4 was identified and further investigations were made into the cause of this (p 331).
- Final project workshop; held on the 9-10th November 2009.

To highlight the extent of review and revision of the model throughout the duration of the project, the current model version of the QMRA is Version 27.

The validation of the intervention analysis is particularly difficult as there are no validation data with which to compare the model results. In addition, with such a complex and non-linear model, it is only really possible to assess whether the resulting trend is reasonable, rather than the *absolute* reduction.

Given the opportunity to revise the report a number of typographical/formatting areas have also been addressed. These amendments have not been documented below. The page numbers for the changes to the QMRA report document relate to the original version of the report (dated 9th March 2010).

2. Time between the store and home for MS4.

2.1 Description of error

Within the Preparation & Consumption module of the QMRA, the travel time for consumers from the store to the domestic home is considered (see page 246). For MS1 – MS3 it was parameterised using the distribution

$$T_{1,2} = T_{2,2} = T_{3,2} = \Re(G([0, 30, 50, 120], [0.96, 0.02, 0.02]))$$

and for MS4 the distribution was assumed to be

$$T_{4,2} = \Re(BP(10, 45, 300)).$$

The number of *Salmonella* cases for MS4 that are attributable to the 3 pork products considered in the QMRA was identified to be an overestimation during the review process. Therefore, these results were further scrutinised and it was thought that the overestimation was due to the use of a different data set for MS4, which has a long right-hand tail, rather than an error in the model and also the sensitivity of the model to this parameter. This is commented on within the final report (see pages x, 331, 402 of EFSA 2010a)

However during the preparation of scientific papers for submission to peer-reviewed journals, it was identified that there was a unit error, i.e. the time between the store and home had been entered into the MatLab programme in hours rather than minutes. This resulted in a very large time span for transport therefore yielding the opportunity for pathogen growth, giving elevated microbial numbers on the products. Prevalence is unaffected. The mistake only impacts MS4.

2.2 Effect on conclusions of the QMRA

As identified above, the results of the QMRA are sensitive to the parameter describing the transport time between store and home. Therefore, this error **substantially** impacts the estimated number of *Salmonella* cases for MS4 (see Table 1).

Table 1: Number of *Salmonella* cases attributable to pork cuts, minced meat and fermented sausage for MS4. Baseline results

Pork type	Previous (EFSA 2010a)	Revised
Pork cut	13837	1384
Minced meat	14825	56
Fermented sausage	1239	1246
TOTAL	29901	2686

It can be seen that the absolute risk estimates for MS4 are now lower. Where previously MS2 and MS4 stood out in terms of risk of illness and the number of human cases, it is now only MS2 that stands out.

The identification of this error necessitated the re-running of the intervention analysis as MS4 was often chosen as the representative case study. During this process, it has been concluded that although the quantitative conclusions of the intervention analysis do change the qualitative conclusions regarding the effect of interventions do not change, as the relative reductions are similar to those presented in the original report.

2.3 Implemented corrections in QMRA report

The model has been corrected for this error and the analyses re-run for both the baseline model and also the intervention analysis.

Executive Summary

- Page vii. 1st paragraph. Change to text.
- Page vii. Table 1 amended.
- Page vii. Table 2 amended.
- Page viii. Table 3 amended.
- Page x. 2nd paragraph after bullet points. Deleted.
- Page xi. Figure 2 amended.
- Page xv. Figure 4 amended.

Preparation & Consumption

- Page 273. Figure 10.9 amended.
- Page 274. Figure 10.10 amended.
- Page 274. 3rd paragraph. Change to text.
- Page 275. Figure 10.11 amended.
- Page 276. Figure 10.12 amended.
- Page 276. 2nd Paragraph. Change to text
- Page 276. 3rd Paragraph. Change to text
- Page 277. Figure 10.13 amended
- Page 277. 1st paragraph. Change to text.
- Page 278. Figure 10.14 amended.
- Page 278. 1st paragraph. Change to text.
- Page 280. Figure 10.18 amended.
- Page 282. Figure 10.22 amended.

Risk Characterisation

- Page 317. Table 12.2 corrected.
- Page 317. 1st paragraph. Change to text.
- Page 317. 2nd paragraph. Change to text.
- Page 317. Table 12.3 corrected.
- Page 319. Table 12.5 corrected.

- Page 320. 5th paragraph. Change to text.
- Page 320. Table 12.6 amended.
- Page 331. 2nd paragraph deleted.

Intervention Analysis

- Page 355. Figure 13.2 amended.
- Page 356. Figure 13.3 amended.
- Page 357. Figure 13.4 amended.
- Page 359. Figure 13.6 amended.
- Page 360. Figure 13.7 amended.
- Page 362. Figure 13.8 amended.

Discussion

- Page 397. 1st paragraph. Change to text.
- Page 402. 3rd paragraph. Text deleted.

Conclusions

- Page 411. 3rd paragraph Change to text.

2.4 Effect on conclusions of the Scientific Opinion

The Scientific Opinion (EFSA, 2010b) focused on the intervention analysis. Therefore the conclusions of the Scientific Opinion are unaffected by this error.

2.5 Suggested corrections in Scientific Opinion

Section 6. Answers to the Terms of Reference (TOR)

- Page 29. Figure 1 to be replaced with Figure 13.2 (p354) from revised QMRA report.
- Page 42. Figure 3 to be replaced with Figure 13.4 (p356) from revised QMRA report.
- Page 47. Figure 4 to be replaced with Figure 13.3 (p. 355) from revised QMRA report.
- Page 47. Figure 4 legend. Refer to Figure 13.3 in revised QMRA report rather than page 352.

3. Insertion of incorrect graph

3.1 Description of error

The identification of the unit error detailed above necessitated the re-running of the intervention analysis as MS4 was often chosen as the representative case study. During this time the erroneous placement of a graph was identified. In particular, the graph currently presented in Figure 13.4 (page 357), actually presents a post-dehairing intervention, when it should present a pre-chill intervention (as denoted in the Figure legend).

3.2 Effect on conclusions of the QMRA

The effect of the pre-chill intervention is to reduce human cases to over 90% with a 1-log decontamination step, whereas the post-dehair step requires 2-logs to reduce cases by this amount. Therefore, the pre-chill intervention is much more effective than the post-dehair intervention. This change in the result changes the quantitative estimates of reductions as reported in the QMRA report. However, the qualitative conclusions remain the same: applying a decontamination step within the abattoir (pre-chill) is an effective intervention, and combined with farm interventions can achieve a significant decrease in human cases.

3.3 Implemented corrections in QMRA report

In order to correct this error the final report has been amended.

Executive Summary

- Page xiv. 3rd paragraph. Change to text.

- Page xiv. Last paragraph. Change to text.
- Page xiv. List of multiple interventions. First two multiple interventions relate to post-dehair, not pre-chill.
- Page xv. Figure 4 corrected
- Page xv. Figure 4 legend amended.

Intervention analysis

- Page 357. Figure 13.4 corrected (describing the effect of an intervention at pre-chill).
- Page 357. Figure 13.4 legend amended.
- Page 357. Figure 13.5 added, which describes the effect of an intervention at post-dehair
- Page 361. First paragraph. Text amended.
- Page 361. List of multiple interventions. First two multiple interventions relate to post-dehair, not pre-chill.
- Page 364. 2nd paragraph. Change to text.
- Page 365. 4th paragraph. Change to text

Discussion

- Page 404. Fifth paragraph. Change to text.
- Page 407. Second paragraph. Change to text.

Conclusion

- Page 414. Last paragraph. Change to text.
- Page 415. List of multiple interventions. First two multiple interventions relate to post-dehair, not pre-chill.
- Page 415. 2nd paragraph. Change to text.

3.4 Effect on conclusions of the Scientific Opinion

The quantitative conclusions of an intervention at pre-chill are incorrect; however the qualitative conclusions are correct.

3.5 Suggested corrections in Scientific Opinion

Abstract

- Page 1. Change text "…result in a 60-80% reduction….." to "…result in more than 90% reduction…"

Summary

- Page 2. Paragraph 6. Change text "…result in a 60-80% reduction….." to "…result in more than 90% reduction…"
- Page 2. Paragraph 6. Change text "…result in a 0-40% reduction….." to "…would result in more than 80% reduction…"

Section 6. Answers to the Terms of Reference (TOR)

- Page 42. Figure 3 to be replaced with Figure 13.4 (p355) from revised QMRA report.
- Page 42. Legend of Figure 3. Replace last sentence with "For each MS, a log reduction of 1-2 logs appears to be sufficient to reduce cases by over 90%."
- Page 42. Paragraph beneath legend for Figure 3. Change sentence "An intervention that could consistently achieve a one log decontamination of carcasses pre-chill could reduce the number of cases by up to 20-40% in low prevalence MSs (MS1, MS3, MS4), but further reductions (up to two logs; 99%) would be needed in other MSs with higher prevalence (i.e. MS2), as the initial contamination levels are predicted to be

higher" to "An intervention that could consistently achieve a 1-2 log decontamination of carcasses pre-chill could reduce the number of cases by over 90% in all MSs"
- Page 43. BIOHAZ Panel's answer to the terms in reference 6. Change "…would result in a 60–80% reduction…" to "…would result in more than 90% reduction…".
- Page 43. BIOHAZ Panel's answer to the terms in reference 6. Change "…would result in a 0–40% reduction…" to "…would result in more than 80% reduction…".

Conclusions
- Page 53. TOR6. First bullet point. Change "…would result in a 60-80% reduction…" to "…would result in more than 90% reduction…".
- Page 53. TOR6. First bullet point. Change "…would result in a 0-40% reduction…" to "…would result in more than 80% reduction…".

4. Insufficient run-time for cleaning and disinfection intervention.

4.1 Description of error

The identification of the unit error detailed above necessitated the re-running of the intervention analysis as MS4 was often chosen as the representative case study. During this re-running of the cleaning and disinfection intervention it was noted that the result was unreliable.

4.2 Effect on conclusions of the QMRA

Significant reductions in the number of human cases can sometimes be found by applying a C&D intervention, but ultimately over many re-runs the trend is that this intervention does not substantially change slaughter pig prevalence or risk of human illness. Given further analysis it is likely that the effect of the C&D intervention lies within the range of the stochastic variability of the farm transmission model. Therefore, our best judgement is that the C&D intervention has a minimal effect. It was previously considered that increasing cleaning efficiency so that an extra 1-2 logs was consistently removed from the pen environment before repopulation would result in significant reduction in a MS's slaughter pig prevalence. Therefore, this change in result does affect the qualitative conclusions of the consortium: cleaning and disinfection doesn't seem to have a large effect in reducing pig infection. However, as stated in the QMRA report, it is unlikely that current methods of disinfection alone would have achieved the level of decontamination necessary to produce significant reductions in pig infection/human illness as suggested by the initial analysis.

4.3 Implemented corrections in QMRA report

Executive summary
- Page xiii. Second paragraph. Text amended.
- Page xiv. Multiple interventions. Due to the ineffectiveness of C&D (which has the same affect as 3-day downtime) an alternative intervention was included.

Intervention analysis
- Page 357. Last paragraph. Change in text.
- Page 358. Figure 13.5 removed.
- Page 361. Multiple interventions. Due to the ineffectiveness of C&D (which has the same affect as 3-day downtime) an alternative intervention was included.
- Page 361. Last paragraph. Text amended.
- Page 362. Figure 13.8 amended.
- Page 362. Figure 13.8 legend amended.
- Page 364. Last paragraph. Change to text.

Discussion

- Page 404. Third paragraph. Text amended.

Conclusion

- Page 413. Last paragraph. Text amended.
- Page 415. Multiple interventions. Due to the ineffectiveness of C&D (which has the same affect as 3-day downtime) an alternative intervention was included.

4.4 Effect on conclusions of the Scientific Opinion

The Scientific Opinion quotes the conclusions from the QMRA and therefore the Scientific Opinion will also need to be updated where it has concluded that C&D is an effective intervention.

4.5 Suggested corrections in Scientific Opinion

Section 6. Answers to the Terms of Reference (TOR)

- Page 33. TOR4. Suggest that the 4th paragraph is removed. Add sentence "Cleaning and disinfection appeared to have no measurable effect." to the end of the previous paragraph.
- Page 44. Change to 2nd paragraph and bullet points due to change in the multiple interventions investigated. Change to "In order to investigate the impact of multiple interventions we considered a number of combinations of interventions; three are highlighted to show general trends from this preliminary analysis:
  - Change to wet feed and 1 log decontamination post-dehair
  - 1 log modification of dose-response with 1 log decontamination post-dehair
  - Change to wet feed and 1 log decontamination pre-chill"
- Page 44. Change to 3rd paragraph. Remove parentheses "(e.g. changing farms to wet feed and applying a one-log decontamination step pre-chill)".

5. References

EFSA 2010a. Quantitative Microbiological Risk Assessment on *Salmonella* in Slighter and Breeder Pigs: Final Report**.** VLA/RIVM/Food-DTU. Available at http://www.efsa.europa.eu/en/scdocs/doc/46e.pdf. Last accessed 29th September 2010.

EFSA 2010b. EFSA Panel on biological Hazards; Scientific opinion on a Quantitative Microbiological Risk Assessment of *Salmonella* in slaughter and breeder pigs. EFSA journal 2010; **8**(4) 1547. [80 pp]. doi:10.2903/j.efsa.2010.1547. Available online: www.efsa.europa.eu

D. GLOSSARY

5- / 10-fold reduction	80% / 90% reduction
Breeder pig	A pig (sow or boar) of at least six months of age kept for breeding purposes.
Breeding holding	A holding having pigs retained for breeding purposes, it covers nucleus holdings and multiplier holdings. Breeding holdings produce and sell pigs for breeding purposes.
Cross-contamination	The contamination of a carcass (or other unit under investigation) by means of a second agent, which has previously been contaminated by another carcass.
Disease monitoring	The ongoing efforts directed at assessing the health and disease status of a given population. This activity necessitates a system for collecting, processing and summarising data and disseminating information to appropriate agents and individuals.[30]
Disease surveillance	The ongoing, systematic collection and evaluation of data describing the occurrence of spread of disease.[31] It describes a more active system and implies that some form of directed action will be taken if the data indicate a disease level above a certain threshold.[32]
External biosecurity	Involves practices and techniques directed at the prevention of entry of new diseases into a group of animals (includes practices to control feed, incoming pigs, wildlife, rodents, and visitors)
Harvest	The part of the food chain beginning with the transport of the slaughter animals from the farm gate, the lairage phase, slaughtering itself, up to the cooling of the carcasses
High prevalence country	Country with a breeder pig herd prevalence above 10% (used in the QMRA) and in previous EFSA opinion; "medium and higher prevalence status" (EFSA 2006)
Internal biosecurity	Involves practices and techniques that are directed at the prevention or spread of disease within an existing group of animals
Large slaughterhouse	Above 100,000 slaughtered pigs per year; 400 slaughtered pigs per day

30 Martin S.W., Meek A.H. and Willeberg P. (1987). In Veterinary Epidemiology: Principles and Methods, pp. 259-282. Ames, Iowa: Iowa State University Press.

31 World Health Organisation, WHO (2002). Methods for foodborne Disease Surveillance in selected sites. Report of a WHO consultation 18-21 March 2002, Leipzig, Germany. http://whqlibdoc.who.int/hq/2002/WHO_CDS_CSR_EPH_2002.22.pdf

32 World Organisation for Animal Health, OIE (2005). Terrestrial Animal Health Code. 14th Edition, 2005. http://www.oie.int/eng/normes/mcode/en_chapitre_1.1.1.htm

Low prevalence country	Country with a breeder pig herd prevalence below or equal to 10% (used in the QMRA) and in previous EFSA opinion; "low prevalence status" (EFSA 2006).
Pork or pig meat	The flesh of a pig used as food, especially when uncured[33].
Post harvest	The part of the food chain which includes cutting and processing, production of raw, fermented or "safe products" up to retail and consumer levels.
Pre-harvest	The part of the food chain which includes the period when the animals are held on the holding or farm up the the point when the pigs leave the farm and are loaded for transportation to the slaughterhouse
Primary production	The production, rearing or growing of primary products including harvesting, milking and farmed animal production prior to slaughter. It also includes hunting and fishing and the harvesting of wild products[34]
Production holding	A holding selling pigs for fattening or slaughter
QMRA	Quantitative microbiological risk assessment
Sensitivity analysis	Used to assess the relationship between the random variables within the model and the model output. The analysis is carried out using the original distributions found in the baseline model. For example, through the sensitivity analysis, it was concluded that the amount of *Salmonella* shed by a sow is strongly correlated with the prevalence of lymph-node positive pigs at the point of slaughter.
Slaughter pigs	A pig kept for fattening / slaughter purposes
Small slaughterhouse	Minimum of 1 pig per day (specific definition in QMRA report p. 195 Table 9.18)
Uncertainty analysis	Used to assess the confidence we have in the model results. The analysis is carried out by changing the values of either point-values or random variables, such that we perturb the model away from its baseline form. By noting the change in the values of the model results, we can determine how much of an effect the uncertainty about individual parameters might have on the model output.

33 From The Oxford Dictionary of English (2nd edition revised)
34 Regulation 178/2002. OJ L31/01.02.2002 p.1

E. CHANGES MADE IN THE UPDATE OF OPINION

Abstract:

Also according to the QMRA, for each MS, a reduction of two logs (99%) of *Salmonella* numbers on contaminated carcasses would result in more than 90% ~~a 60-80%~~ reduction of the number of human salmonellosis cases attributable to pig meat consumption. The control of *Salmonella* in pig reservoir in the EU is a reasonable objective.

Footnote 1:

On request from the European Commission, Question No EFSA-Q-2006-176, originally adopted on 11 March 2010. After identification of modelling errors in the QMRA report by the consortium (grant beneficiary), this opinion was corrected, the current annex with explanations for the corrections of the errors added, and the corrected opinion adopted on 21 October 2010. The changes were made in Section 6 and corresponding conclusions, and are specified in Appendix C and Appendix E.

Summary:

Theoretically, according to the QMRA following scenarios appear possible (a) by ensuring that breeder pigs are *Salmonella*-free a reduction of 70-80% in high prevalence MSs and 10-20% in low prevalence MSs can be foreseen; (b) by feeding only *Salmonella*-free feedstuffs, a reduction of 10-20% in high prevalence MSs and 60-70% in low prevalence MSs can be foreseen; and (c) by preventing infection from external sources of *Salmonella* (i.e. rodents and birds) a reduction of 10-20% in slaughter pig lymph node prevalence can be foreseen in both high and low prevalence MSs. A hierarchy of control measures is suggested - a high prevalence in breeder pigs needs to be addressed first, followed by control of feed and then control of environmental contamination. Also according to the QMRA, for each MS, a reduction of two logs (99%) of *Salmonella* numbers on contaminated carcasses would result in a more than 90~~60-80~~% reduction of the number of human salmonellosis cases attributable to pig meat consumption. A reduction of one log would result in more than 80~~a 0-40~~% reduction of human cases. This could be achieved through measures preventing direct and/or indirect faecal contamination during transport, lairage and, particularly, slaughter and dressing processes; and/or by effective carcass decontamination.

6.1.2 The effect of reduction of *Salmonella* prevalence in pigs on human *Salmonella* risk

Figure 1 graphs deleted. New graphs inserted.

6.1.4 Reduction of prevalence in slaughter pigs by control measures at farm level (pre-harvest stage)

Modifying the pig dose-response relationship to Salmonella exposure, perhaps by changing feed type, adding organic acids to feed/water, or vaccination, could have a significant effect in reducing

slaughter pig prevalence within a MS, which would subsequently reduce the number of human cases. However, a large increase in this dose-response relationship – broadly speaking increasing the resistance of ALL of a MS's pigs such that an extra half-log to a log dose is needed to cause the same previous probability of infection – would be needed to see a significant change in the MS slaughter pig prevalence. This type of effect has rarely been described in the literature and it is debatable whether such an effect could be achieved consistently at a national herd level. Cleaning and disinfection appeared to have no ~~measurable~~ effect.

~~*A similar conclusion can be reached for increased cleaning – significant reductions could be achieved in a MS' slaughter pig prevalence if cleaning efficiency was increased so that an extra 1-2 logs was consistently removed from the pen environment before repopulation, but so far these improvements have only been trialled on a small scale.*~~

6.1.6 Expected reduction of *Salmonella* cases in humans by control measures during transport, lairage and slaughter

Figure 3 graphs deleted. New graphs inserted.

Figure 3: *Effect of reducing concentrations across all contaminated carcasses in each MS by one, two, and three logs immediately before chilling of the carcass (pig meat cuts – blue, minced meat – green and fermented sausage – red). For each MS, a ~~log~~ reduction of two logs appears to be sufficient to reduce cases by over 90 ~~approximately 60-80~~%*[26].

Marked reductions can be achieved by preventing faecal leakage or applying some decontamination measure at the slaughterhouse. An intervention that could consistently achieve a two~~one~~ log decontamination of carcasses pre-chill could reduce the number of cases by over 90~~up to 20-40~~% in all~~low prevalence~~ MSs ~~(MS1, MS3, MS4), but further reductions (up to two logs; 99%) would be needed in other MSs with higher prevalence (i.e. MS2), as the initial contamination levels are predicted to be higher~~. Further reductions can be achieved by further reducing concentrations on carcasses at pre-chill (e.g. a reduction of three logs) with all case study MSs predicted to achieve a very high reduction (95-100%) in their number of cases. Practical non-chemical interventions have been shown to produce reductions in the order of one to two logs (90-99%) (Christiansen et al., 2009). If such interventions are shown to be as effective when scaled up and applied across a MS's slaughterhouses, it is concluded that a control measure that reduces Salmonella concentration on carcasses pre-chill would be a viable option for reducing the number of human salmonellosis cases."

6.2 Consideration of multiple interventions

In order to investigate the impact of multiple interventions we considered a number of ~~three~~ combinations of interventions; three are highlighted to show general trends from this preliminary analysis:

1. *Change to wet feed and one log decontamination post-dehair~~pre-chill~~*
2. *One log modification of dose-response with one log decontamination post-dehair~~pre-chill~~*
3. *Change to wet feed and ~~Three day downtime with~~ one log decontamination pre-chill*

The analysis was carried out for MS4 only and it is concluded that a combination of interventions can, if applied judiciously, produce reductions greater than the sum of the individual interventions alone. The major reason for this is that both interventions ~~(e.g. changing farms to wet feed and applying a one log decontamination step pre-chill)~~ will affect the contamination level of carcasses. We also predict similar results for MS1, MS2 and MS3 although, of course, the impact of the combination of interventions that achieve the greatest reductions will be dependent on the situation within a particular MS, in particular the contamination levels of carcasses.

6.3.1 Relative contribution of Salmonella infections in breeder pigs on Salmonella prevalence in slaughter pigs

Figure 4 graph deleted. New graph inserted.

Figure 4: *The effect of breeding pig herd prevalence on the national slaughter pig prevalence (right-hand axes) and the average risk of illness per serving in humans (left-hand axes).~~The effect of breeder pig herd prevalence on the national slaughter pig lymph node prevalence (right-hand axes) and the average risk of illness per serving in humans (left-hand axes). Correlation coefficient of 0.457. (page 352 QMRA report)~~*

Conclusions:

TOR 6: A quantitative estimation at Community level is requested of the expected reduction of *Salmonella* cases in humans (or pig meat) by the most important potential control options during transport, at lairage or during the slaughter process

- For each MS, a reduction of two logs (99%) of *Salmonella* numbers on contaminated carcasses would result in more than 90~~a 60 80~~% reduction of the number of human salmonellosis cases attributable to pig meat consumption. A reduction of one log (90%) would result in more than 80~~a 0 40~~% reduction of human cases.

BIOHAZ Panel's answer to the terms of reference 6

For each MS, a reduction of two logs (99%) of *Salmonella* numbers on contaminated carcasses would result in more than 90~~a 60 80~~% reduction of the number of human salmonellosis cases attributable to pig meat consumption. A reduction of one log would result in more than~~a 0 40~~ 80% reduction of human cases.
